PART 158—DATA REQUIREMENTS FOR REGISTRATION

Subpart A—General Provisions

Subpart B—How to Use Data Tables

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Subpart D—Data Requirement Tables

AUTHORITY: 7 U.S.C. 136–136y.

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Subpart A—General Provisions

§ 158.20 Overview.

(a) *Legal authority.* These requirements are promulgated under the authority of sections 3, 5, 12, and 25 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136–136y).

(b) *Purposes of this part.* (1) The primary purpose of this part is to specify the types and minimum amounts of data and information the Agency requires in order to make regulatory judgments about the risks and benefits of various kinds of pesticide products under the criteria set forth in FIFRA sections 3(c)(5) (C) and (D) and 3(c)(7).

(2) This part also specifies the types and minimum amounts of data and information the Agency requires to decide whether to approve applications for experimental use permits under FIFRA section 5.

(3) Finally, this part specifies the types and minimum amounts of data and information that an applicant for registration, amended registration, or reregistration must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(D) and sections 3(c)(5)(B) or 3(c)(7). Use of the term ''registration'' in this part will pertain to new registrations and amended registrations as well as reregistration accomplished under section 3(g), unless stated otherwise.

(c) *Availability of related guidelines.* The data requirements for pesticide registration specified in this part pertain to product chemistry, residue chemistry, environmental fate, toxicology, reentry protection, aerial drift evaluation, wildlife and aquatic organisms, plant protection, nontarget insects, product performance, and biochemical and microbial pesticides. The standards for conducting acceptable tests, guidance on evaluation and reporting of data, further guidance on when data are required, definition of most terms, and examples of protocols are not specified in this part. This information is available in advisory documents (collectively referred to as Pesticide Assessment Guidelines) through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (telephone: 703–487–4650).

§ 158.25 Applicability of data requirements.

(a) Some kinds of data and information are specified in subparts C and D of this part as ''required'' (''R'') for the evaluation of some or all types of products. Other kinds of data and information are specified in those sections as ''conditionally required'' (''CR''), that is, they are required if the product's proposed pattern of use, results of other tests, or other pertinent factors meet the criteria specified in those sections. The terms ''required'' and ''conditionally required'' are further discussed in §§ 158.100 and 158.101.

(b) The Agency recognizes that certain data requirements may not be applicable to (or should be waived for) some products, and has made provisions for such cases in this part as specified in § 158.35 *Flexibility of the data requirements,* § 158.40 *Consultation with the Agency,* § 158.45 *Waivers,* and § 158.60 *Minor uses.*

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 158.30 Timing of the imposition of data requirements.

This part establishes requirements for the types of data which are necessary to support the unconditional registration of a pesticide product under section 3(c)(5) of the Act. While every registered pesticide product must eventually be supported by the data required by part 158, when an applicant or registrant must initially satisfy these data requirements depends on the factors listed below in this section.

(a) *Existing Registrations.* A registrant of a currently registered pesticide product is not obligated to satisfy any data requirement in part 158 with respect to that product until he receives a notice under section 3(c)(2)(B) of the Act that additional data are required to support the continued registration of the product, until he applies for an amendment to the registration, or until the product is subject to reregistration.

(b) *Applications.* The amount of data required by the Agency to evaluate an application for initial or amended registration depends on whether the product is being reviewed under section 3(c)(5) of the Act (unconditional registration) or section 3(c)(7) of the Act (conditional registration). Refer to § 152.111 of this chapter or consult with the appropriate EPA Product Manager to determine under which section of the Act the application will be reviewed. The following paragraphs identify, for each different type of application, the minimum amount of data that must be available for EPA review to permit EPA to make the statutory risk-benefit determinations required by section 3(c)(5) or 3(c)(7) of the Act. In addition to satisfying these minimum data requirements, applicants may be required to submit or cite additional data, either to permit EPA to assess the safety or efficacy of the product (refer to § 158.75) or to comply with the statutory requirements of section 3(c)(1)(D) of the Act, or both.

(1) *Applications for unconditional registration under section 3(c)(5) of the Act.* EPA will not approve an application for unconditional registration unless all data required by this part which have not been waived are available for EPA to review.

(2) *Applications for conditional registration of a new chemical under section 3(c)(7)(C) of the Act.* EPA will not approve an application for conditional registration of a pesticide containing an active ingredient not contained in any currently registered product unless data required by this part are available for EPA to review except for:

(i) Those data for which the requirement has been waived.

(ii) Those data for which the requirement was imposed so recently that the applicant has not had sufficient time to produce the data.

(3) *Applications for conditional registration of products which are identical or substantially similar to currently registered products under section 3(c)(7)(A) of the Act.* EPA will not approve an application for conditional registration of a pecticide product which is identical or substantially similar to a currently registered pesticide unless the following data are available for EPA to review:

(i) Product chemistry data, as required by subpart C of this part.

(ii) Product performance data, to the extent required by § 158.160.

(4) *Applications for conditional registration of new uses of currently registered products under section 3(c)(7)(B) of the Act.* EPA will not approve an application for registration of a pesticide for a new use of a currently registered pesticide product unless the following data are available for EPA to review:

(i) Product chemistry data, as required by subpart C of this part.

(ii) Product performance data, to the extent required by § 158.160.

(iii) Other data pertaining solely to the new use. The applicant may generally determine which data pertain solely to the new use by comparing the data requirements for all existing uses of all currently registered products containing the same active ingredient(s) with those for all uses including the new use. Any differences are attributable to the new use and must be submitted with the application.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.32 Format of data submission.

(a) *Transmittal document*. All data submitted at the same time and for review in support of a single administrative action (e.g., an application for registration, reregistration, experimental use permit, or in response to a requirement for data under the authority of FIFRA sec. 3(c)(2)(B), must be accompanied by a single transmittal document including the following information:

(1) The identity of the submitter, or the identity of each joint submitter and of the agent for joint submitters;

(2) The date of the submission;

(3) The identification of the Agency action in support of which the data are being submitted, such as the registration number or file symbol, petition number, experimental use permit number, or registration standard review; and

(4) A bibliography of all specific documents included in the submission and covered by the transmittal.

(b) *Individual studies*. (1) All data must be submitted in the form of individual studies. Unless otherwise specified by the Agency, each study should address a single data requirement, and be listed separately in the bibliography.

(2) Each study must include the following elements in addition to the study itself:

(i) A title page, as described in paragraph (c) of this section;

(ii) A Statement of Data Confidentiality Claims and, if desired, a Supplemental Statement of Data Confidentiality Claims, in accordance with § 158.33;

(iii) A certification with respect to Good Laboratory Practice standards, if required by § 160.12 of this chapter;

(iv) If the original study is not in the English language, a complete and accurate English translation under the same cover; and

(v) If the study is of a type listed in § 158.34(b), the statement prescribed by paragraph (c) of that section.

(3) Three identical copies of each study must be submitted. If the study is submitted in conjunction with a pending Special Review or Registration Standard under development, four copies must be submitted. Three copies must be identical and must conform to the requirements of § 158.33 with respect to claims of confidentiality. The fourth copy will be placed in the public docket and must conform to the requirements of § 154.15(c) of this chapter or § 155.30(c) of this chapter with respect to claimed confidential business information.

(4) All copies must be in black ink on uniform pages of white, 8½ × 11 inch paper. Copies must have high contrast and good resolution for microfilming. Frayed or oversize pages and glued bindings are not acceptable.

(c) *Contents of title page*. Each individual study must have a title page bearing the following identifying information:

(1) The title of the study, including identification of the substance(s) tested and the test name or data requirement addressed;

(2) The author(s) of the study;

(3) The date the study was completed;

(4) If the study was performed in a laboratory, the name and address of the laboratory and any laboratory project numbers or other identifying codes;

(5) If the study is a commentary on or supplement to another previously submitted study, full identification of the other study with which it should be associated in review; and

(6) If the study is a reprint of a published document, all relevant facts of publication, such as the journal title, volume, issue, inclusive page numbers, and date of publication.

(d) *EPA identification number*. EPA will assign each study an EPA Master Record Identification (MRID) number, and will promptly notify the submitter of the number assigned. This number should be used in all further communications with the Agency about the study.

(e) *Reference to previously submitted data*. Data which previously have been submitted need not be resubmitted unless resubmission is specifically requested by the Agency. If an applicant or registrant wishes the Agency to consider such data in the review of an Agency action, he should cite the data by providing:

(1) The title or adequate description of the study;

(2) The transmittal information required by paragraph (a) (1), (2), and (3) of this section; and

(3) The MRID number assigned in accordance with paragraph (d) of this section.

[53 FR 15991, May 4, 1988]

§ 158.33 Procedures for claims of confidentiality of data.

(a) *General*. A data submitter must clearly identify any information which he claims is entitled to confidential treatment under FIFRA sec. 10. The procedures in this section must be followed to assert a claim of confidentiality.

(b) *Claims of confidentiality for information described by FIFRA sec. 10(d)(1) (A), (B), and (C)*. Any information claimed to be confidential under FIFRA sec. 10(d)(1) (A) through (C) must be submitted in accordance with the following procedures:

(1) The information must be contained in a separate attachment to the study. If any information is included in the body of the study rather than in the confidential attachment, the submitter waives a

claim of confidentiality for such information under FIFRA sec. 10(d)(1) (A), (B), or (C).

(2) The attachment must have a cover page which is clearly marked to indicate that the material contained in the attachment falls within the scope of FIFRA sec. 10(d)(1) (A), (B), or (C).

(3) Each item in the attachment must be numbered. For each item, the submitter must cite the applicable portion of FIFRA sec. 10(d)(1) (A), (B), or (C) on which the claim of confidentiality is based. In addition, for each item, the submitter must provide a list of page numbers in the study where the item is cited (i.e., identified by number).

(4) Each item in the attachment must be referenced in the body of the study by its number in the attachment.

(5) The following statement must appear on the Statement of Data Confidentiality Claims:

> Information claimed confidential on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

The statement must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

(c) *No claim of confidentiality under FIFRA sec. 10(d)(1)(A), (B), or (C).* If no claim of confidentiality is being made for information described by FIFRA sec. 10(d)(1)(A), (B), or (C), or if such information is not contained in the body of the study, the Statement of Data Confidentiality Claims must include the following statement:

> No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C).

This statement must bear the name, title and signature of the submitter or his properly designated agent, and the date of signature.

(d) *Claim of confidentiality for information not described by FIFRA sec. 10(d)(1) (A), (B), or (C).* Any information not described by FIFRA sec. 10(d)(1) (A), (B), or (C) for which a claim of confidentiality is made must be submitted in accordance with the following procedures:

(1) The information must be clearly marked in the body of the study as being claimed confidential.

(2) A separate Supplemental Statement of Data Confidentiality Claims must be submitted identifying by page and line number the location within the study of each item claimed confidential, and stating the basis for the claim.

(3) The Supplemental Statement of Data Confidentiality Claims must bear the name, title, and signature of the submitter or his properly designated agent, and the date of signature.

[53 FR 15991, May 4, 1988]

§ 158.34 Flagging of studies for potential adverse effects.

(a) Any person who submits a study of a type listed in paragraph (b) of this section to support an application for new or amended registration, or to satisfy a requirement imposed under FIFRA sec. 3(c)(2)(B), must submit with the study a statement in accordance with paragraph (c) of this section.

(b) The following table indicates that study types and the criteria to be applied to each. Column 1 lists the study types by name. Column 2 lists the associated Pesticide Assessment Guideline number. Column 3 lists the criteria applicable to each type of study. Column 4 lists the reporting code to be included in the statement specified in § 158.34(c) when any criterion is met or exceeded.

TABLE—FLAGGING CRITERIA

Toxicity studies	Pesticide assessment guidelines No.	Criteria	Reporting code
Oncogenicity [or combined oncogenicity/chronic feeding study]	83–2	Treated animals show any of the following:	
or			
Subchronic feeding study	82–1	An incidence of neoplasms in male or female animals which increases with dose;	1
		or	
		A statistically significant ($p \leq 0.05$) incidence of any type of neoplasm in any test group (male or female animals at any dose level) compared to concurrent control animals of the same sex;	2
		or	
		An increase in any type of uncommon or rare neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	3
		or	

TABLE—FLAGGING CRITERIA—Continued

Toxicity studies	Pesticide assessment guidelines No.	Criteria	Reporting code
		A decrease in the time to development of any type of neoplasms in any test group (male or female animals at any dose level) compared to concurrent control animals	4
Teratogenicity	83–3	When compared with concurrent controls, treated animals show a dose-related increase in malformations (or deaths) on a litter basis in the absence of significant maternal toxicity at the same dose levels	5
Neurotoxicity	81–7	When compared with controls, treated animals show a response indicative of acute delayed neurotoxicity	6
Chronic feeding study or combined chronic feeding/ oncogenicity study	83–1	Cholinesterase inhibition NOEL less than 10 times the current existing ADI.	7
		or	
		General (systemic) toxicity NOEL less than 100 times the current existing ADI.	8
Reproduction study	83–4	Reproductive effects NOEL less than 100 times the current ADI	9
Subchronic feeding study	82–1	Cholinesterase inhibition NOEL less than 100 times the current existing ADI.	10
		or	
		General (systemic) toxicity NOEL less than 1000 times the current existing ADI.	11

(c) *Identification of studies.* For each study of a type identified in paragraph (b) of this section, the applicant (or registrant in the case of information submitted under FIFRA sec. 3(c)(2)(B)) shall include the appropriate one of the following two statements, together with the signature of the authorized representative of the company, and the date of signature:

(1) ''I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study neither meets nor exceeds any of the applicable criteria.''

(2) ''I have applied the criteria of 40 CFR 158.34 for flagging studies for potential adverse effects to the results of the attached study. This study meets or exceeds the criteria numbered [insert all applicable reporting codes.]''

[53 FR 15992, May 4, 1988, as amended at 58 FR 34203, June 23, 1993]

§ 158.35 Flexibility of the data requirements.

Several provisions of this part provide EPA flexibility in requiring (or not requiring) data and information for the purposes specified in § 158.20(b). These provisions are summarized in this section and discussed elsewhere in this part.

(a) The Agency encourages each applicant, particularly a person applying for registration for the first time, to consult with the Product Manager for his product to resolve questions relating to the protocols or the data requirements before undertaking extensive testing under § 158.40.

(b) Any applicant who believes that a data requirement is inapplicable to a specific pesticide product may request a waiver of a data requirement under § 158.45.

(c) The Agency may require an applicant to provide additional data or information beyond that specified in subparts C and D of this part when these data are not sufficient to permit EPA to evaluate the applicant's product under § 158.75.

(d) Several policies are in effect that govern the data requirements for registration of products having minor uses. These policies reduce substantially the data requirements that need to be met on the basis of limited exposures and economic equity, and allow case-by-case decision making to determine the specific needs for each kind of use under § 158.60.

(e) The data requirements and guidelines are not static documents. Section 3(c)(2) of FIFRA states that the administrator ''shall revise such guidelines from time to time.'' Therefore, the data requirements and guidelines will be revised periodically to reflect new scientific knowledge, new trends in

pesticide development, and new Agency policies under § 158.80.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 158.40 Consultation with the Agency.

This part establishes data requirements applicable to various general use patterns of pesticide products, but some unique or unanticipated aspect of a proposed product's use pattern or composition may result in the need for conferences between registration applicants and the Agency. Such conferences may be initiated by the Agency or by registration applicants. Applicants are expected to contact their respective Product Managers to arrange discussions. The Agency welcomes suggestions for changes to improve the clarity, accuracy, or some other aspect of the data requirements set forth in this part. Specific suggestions should be forwarded to the Director of the Hazard Evaluation Division.

§ 158.45 Waivers.

(a) *Rationale and policy.* (1) The data requirements specified in this part as applicable to a category of products will not always be appropriate for every product in that category. Some products may have unusual physical, chemical, or biological properties or atypical use patterns which would make particular data requirements inappropriate, either because it would not be possible to generate the required data or because the data would not be useful in the Agency's evaluation of the risks or benefits of the product. The Agency will waive data requirements it finds are inappropriate, but will ensure that sufficient data are available to make the determinations required by the applicable statutory standards.

(2) The Agency will waive data requirements on a case-by-case basis in response to specific written requests by applicants. Because of the wide variety of types and use patterns of pesticides, it is impossible to spell out all of the circumstances which might serve as a basis for waiving data requirements. The Agency, however, will take into account, as appropriate, the factors enumerated in sections 3(c)(2)(A) and 25(a)(1) of FIFRA.

(b) *Procedure for requesting waiver.* (1) An applicant should discuss his plans to request a waiver with the EPA Product Manager responsible for his product before developing and submitting extensive support information for the request.

(2) To request a waiver, an applicant must submit a written request to the appropriate Product Manager. The request must specifically identify the data requirement for which a waiver is requested, explain why he thinks data requirement(s) should be waived, describe any unsuccessful attempts to generate the required data, furnish any other information which he believes would support the request, and when appropriate, suggest alternative means of obtaining data to address the concern which underlies the data requirement.

(c) *Notification of waiver decision.* The Agency will review each waiver request and inform the applicant in writing of its decision. In addition, for decisions that could apply to more than a specific product, the Agency may choose to send a notice to all registrants or to publish a notice in the FEDERAL REGISTER announcing its decision. An Agency decision denying a written request to waive a data requirement shall constitute final Agency action for purposes of FIFRA section 16(a).

(d) *Availability of waiver decisions.* Agency decisions under this section granting waiver requests will be available to the public at the Office of Pesticide Programs Reading Room, Rm. 236, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202 from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays. Any person may obtain a copy of any waiver decision by written request in the manner set forth in 40 CFR part 2.

§ 158.50 Formulators' exemption.

(a) FIFRA section 3(c)(2)(D) provides that an applicant for registration of an end-use pesticide product need not submit or cite any data that pertain to the safety of another registered pesticide product which is purchased by the applicant and used in the manufacture or formulation of the product for which registration is sought.

(b) This exemption applies only to data concerning safety of a product or its ingredients, not to efficacy data. Data concerning safety includes toxicity, metabolism, environmental fate, product chemistry, and residue chemistry data.

(c) This exemption does not apply to data concerning the safety of the applicant's end-use product itself, unless the composition of the applicant's product and that of the purchased product are identical, i.e., data which this part indicates must be developed by tests using the end-use product for which registration is sought as the test substance. These requirements can be identified by the notation ''EP*'' in the ''test substance'' column of the tables in subparts C and D of this part and these are the minimum data requirements that the applicant described in paragraph (a) of this section (i.e., the ''formulator'') must satisfy.

(d) The data to which this exemption applies usually will concern the safety of one or more of the end-use product's active ingredients, specifically, those active ingredients which are contained in the purchased product. These data requirements normally can be identified by the notations ''TGAI'' (technical grade of active ingredient), ''PAI'' (pure active ingredients), ''PAIRA'' (pure

active ingredient, radiolabeled), or ''TEP'' (typical end-use product) in the ''test substance'' column of the tables in subparts C and D of this part.

(e) EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulator's exemption with respect to a data requirement concerning the safety of an ingredient of his product only if:

(1) His application indicates that the ingredient's presence in his product is attributable solely to his purchase from another person of an identified, registered product containing that ingredient and his use of the purchased product in formulating his product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product with any use for which the applicant's product will be labeled; or

(3) The purchased end-use product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(f) Notwithstanding FIFRA section 3(c)(2)(D), EPA will not approve an application unless there is available to EPA for its review whatever data is necessary in order to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7).

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 158.55 Agricultural vs. non-agricultural pesticides.

Section 25(a)(1) of FIFRA instructs the Administrator to ''take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides.'' This part distinguishes the various classes of pesticide use (e.g., crop *vs.* non-crop) and the corresponding data necessary to support registration under FIFRA. This information is present in each data requirement table. In addition, the Use Pattern Index (appendix A) is a comprehensive list of pesticide use patterns, cross-referenced to the general use patterns appearing in the tables; the index will further assist the reader in distinguishing agricultural versus non-agricultural uses of pesticides.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 158.60 Minor uses.

(a) *Minor use policy.* A minor use of a pesticide is a use on a ''minor crop'' (a crop which is planted on a small total amount of acreage) or a use which is otherwise limited such that the potential market volume of the product for that use is inherently small. EPA's policy concerning data requirements for minor uses of pesticides includes the following elements:

(1) Since the market volume for a minor use of a pesticide is intrinsically low, and the risk associated with the use often is also correspondingly low, EPA will adjust the data requirements concerning the minor use appropriately.

(2) A new data requirement pertinent to both an unregistered minor use and a registered major use will not be applied to a minor use applicant until it is applied to the major use registrations.

(3) EPA will accept extrapolations and regional data to support establishment of individual minor use tolerances.

(4) Group tolerances will be established to assist applicants for registration of products for minor uses as described in 40 CFR 180.34.

(b) *Advice on data requirements to support minor uses.* Applicants for registration are advised to contact the appropriate EPA Product Manager of the Minor Use Officer for advice on developing data to support new applications for minor uses of pesticides.

§ 158.65 Biochemical and microbial pesticides.

Biochemical and microbial pesticides are generally distinguished from conventional chemical pesticides by their unique modes of action, low use volume, target species specificity or natural occurrence. In addition, microbial pesticides are living entities capable of survival, growth reproduction and infection. Biochemical and microbial pesticides are subject to a different set of data requirements, as specified in §§ 158.165 and 158.170, respectively.

(a) *Biochemical pesticides.* Biochemical pesticides include, but are not limited to, products such as semichemicals (e.g. insect pheromones), hormones (e.g., insect juvenile growth hormones), natural plant and insect regulators, and enzymes. When necessary the Agency will evaluate products on an individual basis to determine whether they are biochemical or conventional chemical pesticides.

(b) *Microbial pesticides.* (1) Microbial pesticides include microbial entities such as bacteria, fungi, viruses, and protozoans. The data requirements apply to all microbial pesticides, including those that are naturally-occurring as well as those that are genetically modified. Each ''new'' variety, subspecies, or strain of an already registered microbial pest control agent must be evaluated, and may be subject to additional data requirements.

(2) Novel microbial pesticides (i.e., genetically modified or non-indigenous microbial pesticides) will be subject to additional data or information

requirements on a case-by-case basis depending on the particular micro-organism, its parent micro-organism, the proposed pesticide use pattern, and the manner and extent to which the organism has been genetically modified. Additional requirements may include information on the genetic engineering techniques used, the identity of the inserted or deleted gene segment (base sequence data or enzyme restriction map of the gene), information on the control region of the gene in question, a description of the ''new'' traits or characteristics that are intended to be expressed, tests to evaluate genetic stability and exchange, and/or selected Tier II environmental expression and toxicology tests.

(3) Pest control organisms such as insect predators, nematodes, and macroscopic parasites are exempt from the requirements of FIFRA as authorized by section 25(b) of FIFRA and specified in § 152.20 (a) of this chapter.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 158.70 Acceptable protocols.

The Agency has published Pesticide Assessment Guidelines, as indicated in § 158.20(d), which contain suggested protocols for conducting tests to develop the data required by this part.

(a) *General policy.* Any appropriate protocol may be used provided that it meets the purpose of the test standards specified in the guidelines and provides data of suitable quality and completeness as typified by the protocols cited in the guidelines. Applicants should use the test procedure which is most suitable for evaluation of the particular ingredient, mixture, or product. Accordingly, failure to follow a suggested protocol will not invalidate a test if another appropriate methodology is used.

(b) *Organization for Economic Cooperation and Development (OECD) Protocols.* Tests conducted in accordance with the requirements and recommendations of the applicable OECD protocols can be used to develop data necessary to meet the requirements specified in this part. Readers should note, however, that certain of the OECD recommended test standards, such as test duration and selection of test species, are less restrictive than those recommended by EPA. Therefore, when using the OECD protocols, care should be taken to observe the test standards in a manner such that the data generated by the study will satisfy the requirements of this part.

(c) *Procedures for requesting advice on protocols.* Normally, all contact between the Agency and applicants or registrants is handled by the assigned Product Manager in the Registration Division of the Office of Pesticide Programs. Accordingly, questions concerning protocols should be directed, preferably in writing, to the Product Manager responsible for the registration or application which would be affected.

§ 158.75 Requirements for additional data.

(a) *General policy.* The data routinely required by part 158 may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties of pesticide.

(b) *Policy on test substance.* In general, where the technical grade of the active ingredient is specified as the substance to be tested, tests may be performed using a technical grade which is substantially similar to the technical grade used in the product for which registration is sought. In addition to or in lieu of the testing required in subparts C and D of this part the Administrator will, on a case-by-case basis, require testing to be conducted with:

(1) An analytical pure grade of an active ingredient, with or without radioactive tagging.

(2) The technical grade of an active ingredient.

(3) The representative technical grade of an active ingredient.

(4) An intentionally added inert ingredient in a pesticide product.

(5) A contaminant or impurity of an active or inert ingredient.

(6) A plant or animal metabolite or degradation product of an active or inert ingredient.

(7) The end-use pesticide product.

(8) The end-use pesticide product plus any recommended vehicles and adjuvants.

(9) Any additional substance which could act as a synergist to the product for which registration is sought.

(10) Any combination of substances in paragraphs (b) (1) through (9) of this section.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.80 Acceptability of data.

(a) *General policy.* The Agency will determine whether the data submitted to fulfill the data requirements specified in this part are acceptable. This determination will be based on the design and conduct of the experiment from which the data were derived, and an evaluation of whether the data fulfill the purpose(s) of the data requirement. In evaluating experimental design, the Agency will consider whether generally accepted methods were used, sufficient numbers of meas-

urements were made to achieve statistical reliability, and sufficient controls were built into all phases of the experiment. The Agency will evaluate the conduct of each experiment in terms of whether the study was conducted in conformance with the design, good laboratory practices were observed, and results were reproducible. The Agency will not reject data merely because they were derived from studies which, when initiated were in accordance with an Agency-recommended protocol, even if the Agency subsequently recommends a different protocol, as long as the data fulfill the purposes of the requirements as described in this paragraph.

(b) *Previously developed data.* The Agency will consider that data developed prior to the effective date of this part would be satisfactory to support applications provided good laboratory practices were followed, the data meet the purposes of this part, and the data permit sound scientific judgments to be made. Such data will not be rejected merely because they were not developed in accordance with suggested protocols.

(c) *Data developed in foreign countries.* The Agency considers all applicable data developed from laboratory and field studies anywhere to be suitable to support pesticide registrations except for data from tests which involved field test sites or a test material, such as a native soil, plant, or animal, that is not characteristic of the United States. When studies at test sites or with materials of this type are anticipated, applicants should take steps to assure that United States materials are used or be prepared to supply data or information to demonstrate the lack of substantial or relevant differences between the selected material or test site and the United States material or test site. Once comparability has been established, the Agency will assess the acceptability of the data as described in paragraph (a) of this section.

(d) *Data from monitoring studies.* Certain data are developed to meet the monitoring requirements of FIFRA sections 5, 8 or 20. Applicants may wish to determine whether some of these data may meet the requirements of this part. In addition, data developed independently of FIFRA regulations or requirements may also satisfy data requirements in this part. Consultation with appropriate EPA Product Managers would be helpful if applicants are unsure about suitability of such data.

§ 158.85 Revision of data requirements and guidelines.

(a) Data requirements will be revised from time to time to keep up with policy changes and technology. Revisions to this part will be made in accordance with the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). Changes having a significant impact on the registration process, applicants, testers, or other parties, or on the outcome and evaluation of studies, will be made only after public notice and opportunity for comment. Until final rules reflecting a change have been promulgated, the Agency can implement changes in the data requirements on a case-by-case basis.

(b) The Agency invites registration applicants, registrants, and the general public to suggest changes in the data requirements or the Pesticide Assessment Guidelines. Suggestions may be submitted at any time. Those making suggestions are requested to contact, in writing, the Director of the Hazard Evaluation Division. When suggestions consist of new suggested methods, representative test results should accompany the submittals.

Subpart B—How to Use Data Tables

§ 158.100 How to determine registration data requirements.

To determine the specific kinds of data needed to support the registration of each pesticide product, the registration applicant should:

(a) Refer to subparts C and D (§§ 158.150 through 158.740). These subparts describe the data requirements, including data tables for each subject area. The corresponding subdivisions in the Pesticide Assessment Guidelines are listed in § 158.108.

(b) Select the general use pattern(s) that best covers the use pattern(s) specified on the pesticide product label. Selection of the appropriate general use pattern(s) will usually be obvious. However, unique or ambiguous cases will arise occasionally. These situations may be clarified by reference to the Use Pattern Index presented in the appendix to the Data Requirements for Registration. The applicant can look up a specific use pattern in appendix A and it will be cross referenced to the appropriate general use patterns to be used in each Data Requirement table.

(c) Proceed down the appropriate general use pattern column in the table and note which tests (listed along the left hand side of the table) are required (''R''), conditionally required (''CR'') or usually not required (''—''). After reading through each data requirement table, the applicant will have a complete list of required and conditionally required data for the pesticide product and the substance to be tested in developing data to meet each requirement. The data EPA must have available to review the registration of a specific product consists of all the data designated as required for that product and all the applicable data designated as conditionally required for that product.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15993, May 4, 1988]

§ 158.101 Required vs. conditionally required data.

(a) Data designated as ''required'' (''R'') for products with a given general use pattern are needed by EPA to evaluate the risks or benefits of a product having that use pattern unless the data requirement has been waived under § 158.45 for that particular product or unless the product is covered by a specific exception set forth in a note accompanying the requirement.

(b) Data designated as ''conditionally required'' (''CR'') for products with a given general use pattern are needed by EPA to evaluate the risks or benefits of a product having that use pattern if the product meets the conditions specified in the corresponding notes accompanying the data requirements table. As indicated in the notes, the determination of whether the data must be submitted is based on the product's use pattern, physical or chemical properties, expected exposure of nontarget organisms, and/or results of previous testing (e.g., tier testing). Applicants must evaluate each applicable note to determine whether or not conditionally required data must be submitted as indicated by the conditions and criteria specified in the accompanying notes unless the Agency has granted a waiver request submitted by the registrant in accordance with § 158.45.

(c) For certain of the required or conditionally required data, the ''R'' or ''CR'' designations and are enclosed in brackets (i.e., [R], [CR]). The brackets designate those data that are required or conditionally required to support a product when an experimental use permit is being sought. In all other situations (i.e., other than support of an experimental use permit), the brackets have no meaning and the designations R and CR are equivalent to [R] and [CR], respectively.

[49 FR 42881, Oct. 24, 1984, as amended at 58 FR 34203, June 23, 1993]

§ 158.102 Distinguishing between what data are required and what substance is to be tested.

(a) Readers should be careful to distinguish between what data are required and what substance is to be tested, as specified in this part and in each corresponding section of the guidelines. Each data requirement table specifies whether a particular data requirement is required to support the registration of manufacturing-use products, end-use products, or both. The test substance column specifies which substance is to be subjected to testing. Thus, the data from a certain kind of study may be required to support the registration of each end-use product, but the test substance column may state that the particular test shall be performed using, for example, the technical grade of the active ingredient(s) in the end-use product.

(b) Manufacturing-use products (MP) and end-use products (EP) containing a single active ingredient and no inert ingredients are identical in composition to each other and to the technical grade of the active ingredient (TGAI) from which they were derived, and therefore, the data from a test conducted using any one of these as the test substance (e.g., TGAI) is also suitable to meet the requirement (if any) for the same test to be conducted using either of the other substances (i.e., MP or EP).

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 158.108 Relationship of Pesticide Assessment Guidelines to data requirements.

The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, definition of terms, further guidance on when data are required, and examples of acceptable protocols. They are available through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–487–4650). The following Subdivisions of the Pesticide Assessment Guidelines, referenced to the appropriate sections of this part, are currently available:

Subdivision	Title	NTIS order no.	Corresponding section(s) in this part
D	Product Chemistry	PB83–153890	§§ 158.150–158.190
E	Hazard Evaluation: Wildlife and Aquatic Organisms	PB83–153908	§ 158.490
F	Hazard Evaluation: Humans and Domestic Animals	PB83–153916	§ 158.340
G	Product Performance	PB83–153924	§ 158.640
I	Experimental Use Permits	PB83–153932	§§ 158.20–158.740
J	Hazard Evaluation: Nontarget Plants	PB83–153940	§ 158.540
K	Reentry Protection	PB85–120962	§ 158.390
L	Hazard Evaluation: Nontarget Insect	PB83–153957	§ 158.590
M	Biorational Pesticides	PB83–153965	§§ 158.690–158.740
N	Environmental Fate	PB83–153973	§ 158.290
O	Residue Chemistry	PB83–153961	§ 158.240
R	Spray Drift Evaluation	PB84–189216	§ 158.440

[53 FR 15993, May 4, 1988]

Subpart C—Product Chemistry Data Requirements

SOURCE: 53 FR 15993, May 4, 1988, unless otherwise noted.

§ 158.150 General.

(a) *Applicability.* This subpart describes the product chemistry data that are required to support the registration of each pesticide product. The information specified in this subpart must be submitted with each application for new or amended registration or for reregistration, if it has not been submitted previously or if the previously submitted information is not complete and accurate. References in this subpart to the ''applicant'' include the registrant if the information is required for a registered product.

(b) *Purpose*—(1) *Product composition.* (i) Data on product composition are needed to support the conclusions expressed in the statement of formula. These data include information on the starting materials, production or formulating process, possible formation of impurities, results of preliminary analysis of product samples, a description of analytical methods to identify and quantify ingredients and validation data for such methods. In addition, an applicant is required to certify the limits for ingredients of his product.

(ii) Product composition data are compared to the composition of materials used in required testing under subpart D of this part. This comparison indicates which components of a pesticide product have been evaluated by a particular study, and might lead to a conclusion that another study is needed. Based on conclusions concerning the product's composition and its toxic properties, appropriate use restrictions, labeling requirements, or special packaging requirements may be imposed.

(iii) Product composition data, including certified limits of components, are used to determine whether a product is ''identical or substantially similar'' to another product or ''differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment'' (FIFRA sec. 3(c)(7)(A)). In nearly every case, this determination involves a comparison of the composition of an applicant's product with that of currently registered products.

(2) *Certified limits.* Certified limits required by § 158.175 are used in two ways. First, the Agency considers the certified limits in making the registration determination required by sections 3(c)(5), 3(c)(7) and 3(d) of the Act and making other regulatory decisions required by the Act. Second, the Agency may collect commercial samples of the registered products and analyze them for the active ingredient(s), inert ingredients, or impurities determined by the Agency to be toxicologically significant. If, upon analysis the composition of such a sample is found to differ from that certified, the results may be used by the Agency in regulatory actions under FIFRA sec. 12(a)(1)(C) and other pertinent sections.

(3) *Nominal concentration.* The nominal concentration required by § 158.155 is the amount of active ingredient that is most likely to be present in the product when produced. Unlike the certified limits, which are the outer limits of the range of the product's ingredients and thus are present only in a small proportion of the products, the nominal concentration is the amount that typically is expected to result from the applicant's production or formulating process. The nominal concentration together with production process information is used to gauge the acceptability of the certified limits presented by the applicant. The nominal concentration is used by the Agency as the basis for enforceable certified limits if the applicant has chosen not to specify certified limits of his own (thereby agreeing to abide by the standard limits in § 158.175).

(4) *Physical and chemical characteristics.* (i) Data on the physical and chemical characteristics of pesticide active ingredients and products are used to confirm or provide supportive information on their identity. Such data are also used in reviewing the production or formulating process used to produce the pesticide or product. For example, data that indicate significant changes in production or formulation might indicate the need for additional information on product composition.

(ii) Certain information (e.g., color, odor, physical state) is needed for the Agency to respond to emergency requests for identification of unlabeled pesticides involved in accidents or spills. Physicians, hospitals, and poison control centers also request this information to aid in their identification of materials implicated in poisoning episodes.

(iii) Certain physical and chemical data are used directly in the hazard assessment. These include stability, oxidizing and reducing action, flammability, explodability, storage stability, corrosion, and dielectric breakdown voltage. For example, a study of the corrosion characteristics of a pesticide is needed to evaluate effects of the product formulation on its container. If the pesticide is highly corrosive, measures can be taken to ensure that lids, liners, seams or container sides will not be damaged and cause the contents to leak during storage, transport, handling, or use. The storage stability study provides data on change (or lack of change)

in product composition over time. If certain ingredients decompose, other new chemicals are formed whose toxicity and other characteristics must be considered.

(iv) Certain data are needed as basic or supportive evidence in initiating or evaluating other studies. For example, the octanol/water partition coefficient is used as one of the criteria to determine whether certain fish and wildlife toxicity or accumulation studies must be conducted. Vapor pressure data are needed, among other things, to determine suitable reentry intervals and other label cautions pertaining to worker protection. Data on viscosity and miscibility provide necessary information to support acceptable labeling for tank mix and spray applications.

§ 158.153 Definitions.

The following terms are defined for the purposes of this subpart:

(a) *Active ingredient* means any substance (or group of structurally similar substances, if specified by the Agency) that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant within the meaning of FIFRA sec. 2(a).

(b) *End use product* means a pesticide product whose labeling

(1) Includes directions for use of the product (as distributed or sold, or after combination by the user with other substances) for controlling pests or defoliating, desiccating or regulating growth of plants, and

(2) Does not state that the product may be used to manufacture or formulate other pesticide products.

(c) *Formulation* means

(1) The process of mixing, blending, or dilution of one or more active ingredients with one or more other active or inert ingredients, without an intended chemical reaction, to obtain a manufacturing use product or an end use product, or

(2) The repackaging of any registered product.

(d) *Impurity* means any substance (or group of structurally similar substances if specified by the Agency) in a pesticide product other than an active ingredient or an inert ingredient, including unreacted starting materials, side reaction products, contaminants, and degradation products.

(e) *Impurity associated with an active ingredient* means:

(1) Any impurity present in the technical grade of active ingredient; and

(2) Any impurity which forms in the pesticide product through reactions between the active ingredient and any other component of the product or packaging of the product.

(f) *Inert ingredient* means any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product.

(g) *Integrated system* means a process for producing a pesticide product that:

(1) Contains any active ingredient derived from a source that is not an EPA-registered product; or

(2) Contains any active ingredient that was produced or acquired in a manner that does not permit its inspection by the Agency under FIFRA sec. 9(a) prior to its use in the process.

(h) *Manufacturing use product* means any pesticide product other than an end use product. A product may consist of the technical grade of active ingredient only, or may contain inert ingredients, such as stabilizers or solvents.

(i) *Nominal concentration* means the amount of an ingredient which is expected to be present in a typical sample of a pesticide product at the time the product is produced, expressed as a percentage by weight.

(j) *Starting material* means a substance used to synthesize or purify a technical grade of active ingredient (or the practical equivalent of the technical grade ingredient if the technical grade cannot be isolated) by chemical reaction.

(k) *Technical grade of active ingredient* means a material containing an active ingredient:

(1) Which contains no inert ingredient, other than one used for purification of the active ingredient; and

(2) Which is produced on a commercial or pilot-plant production scale (whether or not it is ever held for sale).

§ 158.155 Product composition.

Information on the composition of the pesticide product must be furnished. The information required by paragraphs (a), (b) and (f) of this section must be provided for each product. In addition, if the product is produced by an integrated system, the information on impurities required by paragraphs (c) and (d) must be provided.

(a) *Active ingredient.* The following information is required for each active ingredient in the product:

(1) If the source of any active ingredient in the product is an EPA-registered product:

(i) The chemical and common name (if any) of the active ingredient, as listed on the source product.

(ii) The nominal concentration of the active ingredient in the product, based upon the nominal concentration of active ingredient in the source product.

(iii) Upper and lower certified limits of the active ingredient in the product, in accordance with § 158.175.

(2) If the source of any active ingredient in the product is not an EPA-registered product:

(i) The chemical name according to Chemical Abstracts Society nomenclature, the CAS Registry Number, and any common names.

(ii) The molecular, structural, and empirical formulae, and the molecular weight or weight range.

(iii) The nominal concentration.

(iv) Upper and lower certified limits in accordance with § 158.175.

(v) The purpose of the ingredient in the formulation.

(b) *Inert ingredients.* The following information is required for each inert ingredient (if any) in the product:

(1) The chemical name of the ingredient according to Chemical Abstracts Society nomenclature, the CAS Registry Number, and any common names (if known). If the chemical identity or chemical composition of an ingredient is not known to the applicant because it is proprietary or trade secret information, the applicant must ensure that the supplier or producer of the ingredient submits to the Agency (or has on file with the Agency) information on the identity or chemical composition of the ingredient. Generally, it is not required that an applicant know the identity of each ingredient in a mixture that he uses in his product. However, in certain circumstances, the Agency may require that the applicant know the identity of a specific ingredient in such a mixture. If the Agency requires specific knowledge of an ingredient, it will notify the applicant in writing.

(2) The nominal concentration in the product.

(3) Upper and lower certified limits in accordance with § 158.175.

(4) The purpose of the ingredient in the formulation.

(c) *Impurities of toxicological significance associated with the active ingredient.* For each impurity associated with the active ingredient that is determined to be toxicologically significant, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) The chemical name of the impurity.

(3) The nominal concentration of the impurity in the product.

(4) A certified upper limit, in accordance with § 158.175.

(d) *Other impurities associated with the active ingredient.* For each other impurity associated with an active ingredient that was found to be present in any sample at a level equal to or greater than 0.1 percent by weight of the technical grade active ingredient, the following information is required:

(1) Identification of the ingredient as an impurity.

(2) Chemical name of the impurity.

(3) The nominal concentration of the impurity in the final product.

(e) *Impurities associated with an inert ingredient.* [Reserved]

(f) *Ingredients that cannot be characterized.* If the identity of any ingredient or impurity cannot be specified as a discrete chemical substance (such as mixtures that cannot be characterized or isomer mixtures), the applicant must provide sufficient information to enable EPA to identify its source and qualitative composition.

§ 158.160 Description of materials used to produce the product.

The following information must be submitted on the materials used to produce the product:

(a) *Products not produced by an integrated system.*

(1) For each active ingredient that is derived from an EPA-registered product:

(i) The name of the EPA-registered product.

(ii) The EPA registration number of that product.

(2) For each inert ingredient:

(i) Each brand name, trade name, or other commercial designation of the ingredient.

(ii) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and, if requested by the Agency, chemical and physical properties) of the ingredient, including a copy of technical specifications, data sheets, or other documents describing the ingredient.

(iii) If requested by the Agency, the name and address of the producer of the ingredient or, if that information is not known to the applicant, the name and address of the supplier of the ingredient.

(b) *Products produced by an integrated system.* (1) The information required by paragraph (a)(1) of this section concerning each active ingredient that is derived from an EPA-registered product (if any).

(2) The following information concerning each active ingredient that is not derived from an EPA-registered product:

(i) The name and address of the producer of the ingredient (if different from the applicant).

(ii) Information on each starting material used to produce the active ingredient, as follows:

(A) Each brand name, trade name, or other commercial designation of the starting material.

(B) The name and address of the person who produces the starting material or, if that information is not known to the applicant, the name and address of each person who supplies the starting material.

(C) All information that the applicant knows (or that is reasonably available to him) concerning the composition (and if requested by the Agency,

chemical or physical properties) of the starting material, including a copy of all technical specifications, data sheets, or other documents describing it.

(3) The information required by paragraph (a)(2) of this section concerning each inert ingredient.

(c) *Additional information.* On a case-by-case basis, the Agency may require additional information on substances used in the production of the product.

§ 158.162 Description of production process.

If the product is produced by an integrated system, the applicant must submit information on the production (reaction) processes used to produce the active ingredients in the product. The applicant must also submit information on the formulation process, in accordance with § 158.165.

(a) Information must be submitted for the current production process for each active ingredient that is not derived from an EPA-registered product. If the production process is not continuous (a single reaction process from starting materials to active ingredient), but is accomplished in stages or by different producers, the information must be provided for each such production process.

(b) The following information must be provided for each process resulting in a separately isolated substance:

(1) the name and address of the producer who uses the process, if not the same as the applicant.

(2) A general characterization of the process (e.g., whether it is a batch or continuous process).

(3) A flow chart of the chemical equations of each intended reaction occurring at each step of the process, the necessary reaction conditions, and the duration of each step and of the entire process.

(4) The identity of the materials used to produce the product, their relative amounts, and the order in which they are added.

(5) A description of the equipment used that may influence the composition of the substance produced.

(6) A description of the conditions (e.g., temperature, pressure, pH, humidity) that are controlled during each step of the process to affect the composition of the substance produced, and the limits that are maintained.

(7) A description of any purification procedures (including procedures to recover or recycle starting materials, intermediates or the substance produced).

(8) A description of the procedures used to assure consistent composition of the substance produced, e.g., calibration of equipment, sampling regimens, analytical methods, and other quality control methods.

§ 158.165 Description of formulation process.

The applicant must provide information on the formulation process of the product (unless the product consists solely of a technical grade of active ingredient), as required by the following sections:

(a) Section 158.162(b)(2), pertaining to characterization of the process.

(b) Section 158.162(b)(4), pertaining to ingredients used in the process.

(c) Section 158.162(b)(5), pertaining to process equipment.

(d) Section 158.162(b)(6), pertaining to the conditions of the process.

(e) Section 158.162(b)(8), pertaining to quality control measures.

§ 158.167 Discussion of formation of impurities.

The applicant must provide a discussion of the impurities that may be present in the product, and why they may be present. The discussion should be based on established chemical theory and on what the applicant knows about the starting materials, technical grade of active ingredient, inert ingredients, and production or formulation process. If the applicant has reason to believe that an impurity that EPA would consider toxicologically significant may be present, the discussion must include an expanded discussion of the possible formation of the impurity and the amounts at which it might be present. The impurities which must be discussed are the following, as applicable:

(a) *Technical grade active ingredients and products produced by an integrated system.* (1) Each impurity associated with the active ingredient which was found to be present in any analysis of the product conducted by or for the applicant.

(2) Each other impurity which the applicant has reason to believe may be present in his product at any time before use at a level equal to or greater than 0.1 percent (1000 ppm) by weight of the technical grade of the active ingredient, based on what he knows about the following:

(i) The composition (or composition range) of each starting material used to produce his product.

(ii) The impurities which he knows are present (or believes are likely to be present) in the starting materials, and the known or presumed level (or range of levels) of those impurities.

(iii) The intended reactions and side reactions which may occur in the production of the product, and the relative amounts of byproduct impurities produced by such reactions.

(iv) The possible degradation of the ingredients in the product after its production but prior to its use.

(v) Post-production reactions between the ingredients in the product.

(vi) The possible migration of components of packaging materials into the pesticide.

(vii) The possible carryover of contaminants from use of production equipment previously used to produce other products or substances.

(viii) The process control, purification and quality control measures used to produce the product.

(b) *Products not produced by an integrated system.* Each impurity associated with the active ingredient which the applicant has reason to believe may be present in the product at any time before use at a level equal to or greater than 0.1 percent (1000 ppm) by weight of the product based on what he knows about the following:

(1) The possible carryover of impurities present in any registered product which serves as the source of any of the product's active ingredients. The identity and level of impurities in the registered source need not be discussed or quantified unless known to the formulator.

(2) The possible carryover of impurities present in the inert ingredients in the product.

(3) Possible reactions occurring during the formulation of the product between any of its active ingredients, between the active ingredients and inert ingredients, or between the active ingredients and the production equipment.

(4) Post-production reactions between any of the product's active ingredients and any other component of the product or its packaging.

(5) Possible migration of packaging materials into the product.

(6) Possible contaminants resulting from earlier use of equipment to produce other products.

(c) *Expanded discussion.* On a case-by-case basis, the Agency may require an expanded discussion of information of impurities:

(1) From other possible chemical reactions;

(2) Involving other ingredients; or

(3) At additional points in the production or formulation process.

§ 158.170 Preliminary analysis.

(a) If the product is produced by an integrated system, the applicant must provide a preliminary analysis of each technical grade of active ingredient contained in the product to identify all impurities present at 0.1 percent or greater of the TGAI. The preliminary analysis should be conducted at the point in the production process after which no further chemical reactions designed to produce or purify the substance are intended.

(b) Based on the preliminary analysis, a statement of the composition of the technical grade of active ingredient must be provided. If the technical grade of active ingredient cannot be isolated, a statement of the composition of the practical equivalent of the technical grade of active ingredient must be submitted.

§ 158.175 Certified limits.

The applicant must propose certified limits for the ingredients in the product. Certified limits become legally binding limits upon approval of the application. Certified limits will apply to the product from the date of production to date of use, unless the product label bears a statement prohibiting use after a certain date, in which case the certified limits will apply only until that date.

(a) *Ingredients for which certified limits are required.* Certified limits are required on the following ingredients of a pesticide product:

(1) An upper and lower limit for each active ingredient.

(2) An upper and lower limit for each inert ingredient.

(3) If the product is a technical grade of active ingredient or is produced by an integrated system, an upper limit for each impurity of toxicological significance associated with the active ingredient and found to be present in any sample of the product.

(4) On a case-by-case basis, certified limits for other ingredients or impurities as specified by EPA.

(b) *EPA determination of certified limits for active and inert ingredients.* (1) Unless the applicant proposes different limits as provided in paragraph (c) of this section, the upper and lower certified limits for active and inert ingredients will be determined by EPA. EPA will calculate the certified limits on the basis of the nominal concentration of the ingredient in the product, according to the table in paragraph (b)(2) of this section.

(2) Table of standard certified limits.

If the nominal concentration (N) for the ingredient is:	The certified limits for that ingredient will be as follows:	
	Upper limit	Lower limit
N ≤ 1.0%	N + 10%N	N · 10%N
1.0% < N ≤ 20.0%	N + 5%N	N · 5%N
20.0% < N ≤ 100.0%.	N + 3%N	N · 3%N

(c) *Applicant proposed limits.* (1) The applicant may propose a certified limit for an active or inert ingredient that differs from the standard certified limit calculated according to paragraph (b)(2) of this section.

(2) If certified limits are required for impurities, the applicant must propose a certified limit. The standard certified limits may not be used for such substances.

(3) Certified limits should:

(i) Be based on a consideration of the variability of the concentration of the ingredient in the prod-

uct when good manufacturing practices and normal quality control procedures are used.

(ii) Allow for all sources of variability likely to be encountered in the production process.

(iii) Take into account the stability of the ingredient in the product and the possible formation of impurities between production and sale of distribution.

(4) The applicant may include an explanation of the basis of his proposed certified limits, including how the certified limits were arrived at (e.g., sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the certified limit for an active or inert ingredient is greater than the standard certified limits.

(d) *Special cases.* If the Agency finds unacceptable any certified limit (either standard or applicant-proposed), the Agency will inform the applicant of its determination and will provide supporting reasons. EPA may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

(1) More precise limits.

(2) More thorough explanation of how the certified limits were determined.

(3) A narrower range between the upper and lower certified limits than that proposed.

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [*product name*], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 158.180 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that is determined to be toxicologically significant.

§ 158.190 Physical and chemical characteristics.

(a) *Table.* Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the physical and chemical characteristics data requirements and the substance to be tested.

Kind of data required	(b) Notes	All general use patterns (requirements are the same for every use pattern)	Test substance		Guidelines reference No.
			Data to support MP	Data to support EP	
Color		[R]	MP and TGAI	EP* and TGAI	63–2
Physical state		[R]	MP and TGAI	EP* and TGAI	63–3
Odor		[R]	MP and TGAI	EP* and TGAI	63–4
Melting point	(1)	[R]	TGAI	TGAI	63–5
Boiling point	(2)	[R]	TGAI	TGAI	63–6
Density, bulk density, or specific gravity.		[R]	MP and TGAI	EP* and TGAI	63–7
Solubility		[R]	TGAI or PAI	TGAI or PAI	63–8
Vapor pressure		[R]	TGAI or PAI	TGAI or PAI	63–9
Dissociation constant.		[R]	TGAI or PAI	TGAI or PAI	63–10
Octanol/water partition coefficient.	(3)	[CR]	PAI	PAI	63–11
pH	(4)	[CR]	MP and TGAI	EP* and TGAI	63–12
Stability		[R]	TGAI	TGAI	63–13
Oxidizing or reducing action.	(5)	[CR]			
Flammability	(6)	[CR]	MP	EP*	63–15
Explodability	(7)	[R]	MP	EP*	63–16
Storage stability		[R]	MP	EP*	63–17
Viscosity	(8)	[CR]	MP	EP*	63–18
Miscibility	(9)	[CR]	MP	EP*	63–19
Corrosion characteristics.		[R]	MP	EP*	63–20
Dielectric breakdown voltage.	(10)	[CR]		EP*	63–21

Kind of data required	(b) Notes	All general use patterns (requirements are the same for every use pattern)	Test substance		Guidelines reference No.
			Data to support MP	Data to support EP	
Other requirements: Submittal of samples.	(11)	[CR]	MP, TGAI, PAI	EP*, TGAI, PAI	64–1

Key: R = Required; CR = Conditionally Required; [ ] = Brackets (i.e. [R],[CR]) indicate data requirements that apply when an experimental use permit is being sought; MP = Manufacturing Use Product, EP* = End Use Product; asterisk indicates those registrants that end-use applicants (i.e. formulators) need not satisfy, if their active ingredient(s) is (are) purchased from a registered source; TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.

(b) Notes.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Required if technical chemical is a solid at room temperature.
(2) Required if technical chemical is a liquid at room temparature.
(3) Required if technical chemical is organic and non-polar.
(4) Required if test substance is dispersible with water.
(5) Required if product contains an oxidizing or reducing agent.
(6) Required if product contains combustible liquids.
(7) Required if product is potentially explosive.
(8) Required if product is a liquid.
(9) Required if product is a emulsifiable liquid and is to be diluted with petroleum solvents.
(10) Required if end-use product is a liquid and is to be used around electrical equipment.
(11) Basic manufacturers are required to provide the Agency with a sample of each TGAI used to formulate a product produced by an integrated system when the new TGAI is first used as a formulating ingredient in products registered under FIFRA. A sample of the active ingredient (PAI) suitable for use as an analytical standard is also required at this time. Samples of end use products produced by an integrated system must be submitted on a case-by-case basis.

[49 FR 42881, Oct. 24, 1984, as amended at 58 FR 34203, June 23, 1993]

Subpart D—Data Requirement Tables

§ 158.202 Purposes of the registration data requirements.

(a) *General.* The data requirements for registration are intended to generate data and information necessary to address concerns pertaining to the identity, composition, potential adverse effects and environmental fate of each pesticide.

(b) [Reserved]

(c) *Residue chemistry.* (1) Residue Chemistry Data are used by the Agency to estimate the exposure of the general population to pesticide residues in food and for setting and enforcing tolerances for pesticide residues in food or feed.

(2) Information on the chemical identity and composition of the pesticide product, the amounts, frequency and time of pesticide application, and results of test on the amount of residues remaining on or in the treated food or feed, are needed to support a finding as to the magnitude and identity of residues which result in food or animal feed as a consequence of a proposed pesticide usage.

(3) Residue chemistry data are also needed to support the adequacy of one or more methods for the enforcement of the tolerance, and to support practicable methods for removing residues that exceed any proposed tolerance.

(d) *Environmental fate*—(1) *General.* The data generated by environmental fate studies are used to: assess the toxicity to man through exposure of humans to pesticide residues remaining after application, either upon reentering treated areas or from consuming inadvertently-contaminated food; assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides. Another specific purpose of the environmental fate data requirements is to help applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.

(2) *Degradation studies.* The data from hydrolysis and photolysis studies are used to determine the rate of pesticide degradation and to identify pesticides that may adversely affect nontarget organisms.

(3) *Metabolism studies.* Data generated from aerobic and anaerobic metabolism studies are used to determine the nature and availability of pesticides to rotational crops and to aid in the evaluation of the persistence of a pesticide.

(4) *Mobility studies.* These data requirements pertain to leaching, adsorption/desorption, and volatility of pesticides. They provide information on the mode of transport and eventual destination of the pesticide in the environment. This information is used to assess potential environmental hazards related to: contamination of human and animal food; loss of usable land and water resources to man through contamination of water (including ground water); and habitat loss of wildlife resulting from pesticide residue movement or transport in the environment.

(5) *Dissipation studies.* The data generated from dissipation studies are used to assess potential environmental hazards (under actual field use conditions) related to: reentry into treated areas; hazards from residues in rotational crop and other food sources; and the loss of land as well as surface and ground water resources.

(6) *Accumulation studies.* Accumulation studies indicate pesticide residue levels in food supplies that originate from wild sources or from rotational crops. Rotational crop studies are necessary to establish realistic crop rotation restrictions and to determine if tolerances may be needed for residues on rotational crops. Data from irrigated crop studies are used to determine the amount of pesticide residues that could be taken up by representative crops irrigated with water containing pesticide residues. These studies allow the Agency to establish label restrictions regarding application of pesticides on sites where the residues can be taken up by irrigated crops. These data also provide information that aids the Agency in establishing any corresponding tolerances that would be needed for residues on such crops. Data from pesticides accumulation studies in fish are used to establish label restrictions to prevent applications in certain sites so that there will be minimal residues entering edible fish or shell fish. These residue data are also used to determine if a tolerance or action level is needed for residues in aquatic animals eaten by humans.

(e) *Hazard to humans and domestic animals.* Data required to assess hazards to humans and domestic animals are derived from a variety of acute, subchronic and chronic toxicity tests, and tests to assess mutagenicity and pesticide metabolism.

(1) *Acute studies.* Determination of acute oral, dermal and inhalation toxicity is usually the initial step in the assessment and evaluation of the toxic characteristics of a pesticide. These data provide information on health hazards likely to arise soon after, and as a result of, short-term exposure. Data from acute studies serve as a basis for classification and precautionary labeling. For example, acute toxicity data are used to calculate farmworker reentry intervals and to develop precautionary label statements pertaining to protective clothing requirements for applicators. They also: provide information used in establishing the appropriate dose levels in subchronic and other studies; provide initial information on the mode of toxic action(s) of a substance; and determine the need for child resistant packaging. Information derived from primary eye and primary dermal irritation studies serves to identify possible hazards from exposure of the eyes, associated mucous membranes and skin.

(2) *Subchronic studies.* Subchronic tests provide information on health hazards that may arise from repeated exposures over a limited period of time. They provide information on target organs and accumulation potential. The resulting data are also useful in selecting dose levels for chronic studies and for establishing safety criteria for human exposure. These tests are not capable of detecting those effects that have a long latency period for expression (e.g., carcinogenicity).

(3) *Chronic studies.* Chronic toxicity (usually conducted by feeding the test substance to the test species) studies are intended to determine the effects of a substance in a mammalian species following prolonged and repeated exposure. Under the conditions of this test, effects which have a long latency period or are cumulative should be detected. The purpose of long-term oncogenicity studies is to observe test animals over most of their life span for the development of neoplastic lesions during or after exposure to various doses of a test substance by an appropriate route of administration.

(4) *Teratogenicity and reproduction studies.* The teratogenicity study is designed to determine the potential of the test substance to induce structural and/or other abnormalities to the fetus as the result of exposure of the mother during pregnancy. Two-generation reproduction testing is designed to provide information concerning the general effects of a test substance on gonadal function, estrus cycles, mating behavior, conception, parturition, lactation, weaning, and the growth and development of the offspring. The study may also provide information about the effects of the test substance on neonatal morbidity, mortality, and preliminary data on teratogenesis and serve as a guide for subsequent tests.

(5) *Mutagenicity studies.* For each test substance a battery of tests are required to assess potential to affect the mammalian cell's genetic components. The objectives underlying the selection of a battery of tests for mutagenicity assessment are:

(i) To detect, with sensitive assay methods, the capacity of a chemical to alter genetic material in cells.

(ii) To determine the relevance of these mutagenic changes to mammals.

(iii) When mutagenic potential is demonstrated, to incorporate these findings in the assessment of heritable effects, oncogenicity, and possibly, other health effects.

(6) *Metabolism studies.* Data from studies on the absorption, distribution, excretion, and metabolism of a pesticide aid in the valuation of test results from other toxicity studies and in the extrapolation of data from animals to man. The main purpose of metabolism studies is to produce data which increase the Agency's understanding of the behavior of the chemical in its consideration of the

human exposure anticipated from intended uses of the pesticide.

(f) *Reentry Protection.* Data required to assess hazard to farm employees resulting from reentry into areas treated with pesticides are derived from studies on toxicity, residue dissipation, and human exposure. Monitoring data generated during exposure studies are used to determine the quantity of pesticide to which people may be exposed after application and to develop reentry intervals.

(g) *Pesticide Spray Drift Evaluation.* Data required to evaluate pesticide spray drift are derived from studies of droplet size spectrum and spray drift field evaluations. These data contribute to development of the overall exposure estimate and along with data on toxicity for humans, fish and wildlife, or plants are used to assess the potential hazard of pesticides to these organisms. A purpose common to all these tests is to provide data which will be used to determine the need for (and appropriate wording for) precautionary labeling to minimize the potential adverse effect to nontarget organisms.

(h) *Hazard to nontarget organisms*—(1) *General.* The information required to assess hazards to nontarget organisms are derived from tests to determine pesticidal effects on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, subacute, reproduction, simulated field, and full field studies arranged in a hierarchial or tier system which progresses from the basic laboratory tests to the applied field tests. The results of each tier of tests must be evaluated to determine the potential of the pesticide to cause adverse effects, and to determine whether further testing is required. A purpose common to all data requirements is to provide data which determines the need for (and appropriate wording for) precautionary label statements to minimize the potential adverse effects to nontarget organisms.

(2) *Short term studies.* The short-term acute and subchronic laboratory studies provide basic toxicity information which serves as a starting point for the hazard assessment. These data are used: to establish acute toxicity levels of the active ingredient to the test organisms; to compare toxicity information with measured or estimated pesticide residues in the environment in order to assess potential impacts on fish, wildlife and other nontarget organisms; and to indicate whether further laboratory and/or field studies are needed.

(3) *Long term and field studies.* Additional studies (i.e., avian, fish, and invertebrate reproduction, lifecycle studies and plant field studies) may be required when basic data and environmental conditions suggest possible problems. Data from these studies are used to: estimate the potential for chronic effects, taking into account the measured or estimated residues in the environment; and to determine if additional field or laboratory data are necessary to further evaluate hazards. Simulated field and/or field data are used to examine acute and chronic adverse effects on captive or monitored fish and wildlife populations under natural or near-natural environments. Such studies are required only when predictions as to possible adverse effects in less extensive studies cannot be made, or when the potential for adverse effects is high.

(i) *Product performance.* Requirements to develop data on product performance provide a mechanism to ensure that pesticide products will control the pests listed on the label and that unnecessary pesticide exposure to the environment will not occur as a result of the use of ineffective products. Specific performance standards are used to validate the efficacy data in the public health areas, including disinfectants used to control microorganisms infectious to man in any area of the inanimate environment and those pesticides used to control vertebrates (such as rodents, birds, bats and skunks) that may directly or indirectly transmit diseases to humans.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, May 4, 1988]

§ 158.240 Residue chemistry data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the residue chemistry data requirements and the substances to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food corp	Nonfood	Food corp	Nonfood						
Chemical identity	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	171–2
Directions for use	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]			171–3
Nature of the residue:													
Plants	(13), (14)	[R]		[R]		[R]			[CR]	[CR]	PAIRA	PAIRA	171–4
Livestock	(3), (13), (14)	[CR]		[CR]		[CR]			[CR]	[CR]	PAIRA and plant metabloites.	PAIRA and plant metabolites.	171–4
Residue analytical method.	(4), (13), (14), (15)	[R]		[R]		[R]			[CR]	[CR]	TGAI and metabolites.	TGAI and metabolites.	171–4
Magnitude of the residue:													
Crop field trials	(13), (14)	[R]		[R]		[R]			[CR]	[CR]	TEP	TEP	171–4
Processed food/feed.	(5), (14)	[CR]		[CR]		[CR]				[CR]	EP	EP	171–4
Meat/milk/poultry/eggs.	(6), (14)	[CR]		[CR]		[CR]				[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	171–4
Potable water	(7)			[R]	[R]						EP	EP	171–4
Fish	(8)			[R]	[R]						EP	EP	171–4
Irrigated crops	(9)			[CR]	[CR]						EP	EP	171–4
Food handling	(10), (14)									[CR]	EP	EP	171–4
Reduction of residue	(11), (14)	[CR]		[CR]		[CR]				[CR]	Residue of concern.	Residue of concern.	171–5
Proposed tolerance	(12), (14)	[R]		[R]		[R]				[CR]	Residue of concern.	Residue of concern.	171–6
Reasonable grounds in support of the petition.	(14)	[R]		[R]		[R]				[CR]			171–7
Submittal of analytical reference standards.	(14)	[R]		[R]		[R]				[CR]	PAIRA	PAIRA	171–13

Key: R=Required data; CR=Conditionally required data; TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radio labeled; EP=End-use product; TEP=Typical end-use product; MP=Manufacturing-use product; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The same chemical identity data as required under Subpart C of this part are required, with emphasis on impurities that could constitute a residue problem.

(2) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

(3) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.

(4) A residue method for enforcement of tolerances is needed whenever a numeric tolerance is proposed. Exemptions from the requirement of a tolerance will also usually require an analytical method. Analytical methods used to enforce residue limits for emergency exemptions, temporary tolerances and permanent tolerances must be available for use by enforcement agencies and thus may not be claimed as confidential business information.

(5) Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance.
(6) Livestock feeding studies are required whenever a pesticide occurs as a residue in a livestock feed. Use involving direct application to livestock, including poultry, will require animal treatment residue studies.
(7) Data on residues in potable water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used (eventually) for drinking purpose, by man or animals.
(8) Data on residue in fish are required whenever a pesticide is to be applied directly to water inhabited by fish.
(9) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.
(10) Data on residues in food/feed in food handling establishments are required whenever a pesticide is to be used in food/feed handling establishments. Disinfectants and sanitizers used in food or feed handling establishment are exempt from this requirement if their residues are regulated by the Food and Drug Administration at 21 CFR 178.1010.
(11) Reduction of residue data are required when the assumption of tolerance level residues would result in predicted exposure at an unsafe level. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure. The Agency recommends that such data be generated to support all pesticides requiring a tolerance in case new data are revealed which indicates the pesticide is more toxic than initially determined.
(12) The proposed tolerance must reflect the maximum residue likely to occur in crops and meat/milk/poultry eggs.
(13) Residue data for outdoor domestic uses are required if home gardens are to be treated and the home garden use pattern is different from the use pattern on which the tolerance was established.
(14) Required to support registration of an indoor use pesticide if such a use could result in residues in food or feed.
(15) For all food uses, data on whether the FDA/USDA multiresidue methodology would detect and identify the pesticide are required.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.290 Environmental fate data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the environmental fate data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Degradation studies-lab													
Hydrolysis		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]		TGAI or PAIRA.	TGAI or PAIRA.	161–1
Photodegradation:													
In water		R	R	R	R			R			TGAI or PAIRA.	TGAI or PAIRA.	161–2
On soil	(1)	CR						CR			TGAI or PAIRA.	TGAI or PAIRA.	161–3
In air	(2)	CR									TGAI or PAIRA.	TGAI or PAIRA.	161–4
Metabolism studies-lab													
Aerobic soil		[R]	[R]			R	R	[R]	R		TGAI or PAIRA.	TGAI or PAIRA.	162–1
Anaerobic aquatic				R	R			R			TGAI or PAIRA.	TGAI or PAIRA.	162–3

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Aerobic aquatic				[R]	[R]						TGAI or PAIRA.	TGAI or PAIRA.	162–4
Mobility studies													
Leaching and adsorption/desorption.		[R]	[R]	R	R	R	R	[R]	R		TGAI or PAIRA.	TGAI or PAIRA.	163–1
Volatility:													
(Lab)	(2)	CR				CR	CR				TEP	TEP	163–2
(Field)	(2)	CR				CR	CR				TEP	TEP	163–3
Dissipation studies-field													
Soil		R	R						R		TEP	TEP	164–1
Aquatic (sediment)				R	R						TEP	TEP	164–2
Forestry								R			TEP	TEP	164–3
Combination and tank mixes.	(2)												164–4
Soil, long-term	(4)	CR		CR							TEP	TEP	164–5
Accumulation studies													
Rotational crops:													
(Confined)	(5)	[CR]		[CR]							PAIRA	PAIRA	165–1
(Field)	(6)	CR		CR							TEP	TEP	165–2
Irrigated crops	(7)			[CR]	CR						TEP	TEP	165–3
In fish	(8)	[CR]	[CR]	[CR]	[CR]			[CR]			TGAI or PAIRA.	TGAI or PAIRA.	165–4
In aquatic non-target organisms.	(8), (9)				CR			CR			TEP	TEP	165–5

Key: R=Required: CR=Conditionally required; [ ]=Brackets (ie. [R], [CR], indicate data requirements that apply when an experimental use permit is being sought; TGAI=Technical grade of the active ingredient, PAIRA="Pure" active ingredient-radio labeled; TEP=typical end use product; EP =End use product.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if use involves application to soils solely by injection of the product into the soil or by incorporation of the product into the soil upon application.

AAAAA(2) Required on case by case basis depending on product use pattern and other pertinent factors.

AAAAA(3) Not required if anaerobic aquatic metabolism study has been conducted.

AAAAA(4) Required if pesticide residues do not readily dissipate in soil.

AAAAA(5) Confined accumulation study is required when it is reasonably foreseeable that any food or feed crop may be subsequently planted on the site of pesticide application.

AAAAA(6) Field accumulation study is required if significant pesticide residue is likely to be present in soil at time of plant crop, as evidenced by residue data obtained from confined accumulation study.

AAAAA(7) Required if it is reasonably foreseeable that water at treated site may be used for irrigation purposes.

AAAAA(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

AAAAA(9) Required unless tolerance or action level for fish has been granted.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988]

§ 158.340 Toxicology data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the toxicology data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Acute testing													
Acute oral toxicity—rat	(1)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	81–1
Acute dermal toxicity	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	81–2
Acute inhalation toxicity—rat.	(16)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	81–3
Primary eye irritation—rabbit.	(2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81–4
Primary dermal irritation	(1), (2)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81–5
Dermal sensitization	(3)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	81–6
Acute delayed neurotoxicity—hen.	(4)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	81–7
Subchronic testing													
90-day feeding studies—rodent and nonrodent.	(17)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	82–1
21-day dermal	(18)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI and EP*.	82–2
90-day dermal	(5), (19)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82–3
90-day inhalation—rat	(6)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82–4
90-day neurotoxicity:													
Hen	(7)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82–5
Mammal	(8)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	82–5
Chronic testing													
Chronic feeding—2 spp. rodent and nonrodent.	(9), (13), (20)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83–1
Oncogenicity study—2 Spp. rat and mouse preferred.	(9), (21)	R	CR	R	CR	R	CR	CR	CR	CR	TGAI	TGAI	83–2
Teratogenicity—2 species.	(10), (15)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83–3
Reproduction, 2-generation.	(11), (14)	[R]	CR	[R]	CR	[R]	CR	CR	CR	CR	TGAI	TGAI	83–4
Mutagenicity testing													
Gene mutation	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84–2
Structural chromosomal aberration.	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84–2
Other genotoxic effects	(22)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	84–4

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Special testing													
General metabolism	(23)	R	CR	R	CR	R	CR	CR	CR	CR	PAI or PAIRA.	PAI or PAIRA.	85–1
Dermal penetration	(24)	CR	CR	CR	CR	CR	CR	CR	CR	CR	Choice	Choice	85–2
Domestic animal safety ..	(12)	CR	CR	CR	CR	.....	.....	CR	CR	.....	Choice	Choice	86–1

AAAAAKey: R=Required data; CR=Conditionally required; [ ]=Brackets (ie [R], [CR] indicate data requirements that apply when an experimental use permit is being sought; MP=manufacturing-use product; EP*=End-Use Product; (asterisk identifies those data requirements that end-use applicants (i.e. ''formulators'') must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; PAI=''Pure'' active ingredient; PAIRA=''Pure'' active ingredient, radio-labeled; Choice=choice of several test substances, depending on studies required.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Not required if test material is a gas or highly volatile.

(2) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified as toxicity category I on the basis of potential eye and dermal irritation effects.

(3) Required unless repeated dermal exposure does not occur under conditions of use.

(4) Not required unless test material, is an organophosphate, or a metabolite or degradation product thereof which causes acetyl cholinesterase depression or is structurally related to a substance that causes delayed neurotoxicity.

(5) Required if use involves purposeful dermal application to, or prolonged exposure of, human skin.

(6) Required if use may result in repeated inhalation exposure at a concentration likely to be toxic. A test with duration of 21 days is required if pesticide is used on tobacco.

(7) Required if acute delayed neurotoxicity test showed neuropathy or neurotoxicity or if closely related structural to a compound which can induce these effects.

(8) Required if acute oral, dermal, or inhalation studies showed neuropathy or neurotoxicity.

(9)(i) Studies designed to simultaneously meet the requirements of both the chronic feeding and oncogenicity studies (i.e., a combined study) can be conducted.

(ii) Minimum acceptable test durations for chronic feeding and oncogenicity studies are as follows:

(A) Chronic rodent feeding study (food use pesticides)—24 months.

(B) Chronic rodent feeding study (non-food pesticides)—12 months is usually sufficient.

(C) Chronic nonrodent (i.e., dog) feeding study—12 months.

(D) Mouse oncogenicity study—18 months.

(E) Rat oncogenicity study—24 months.

(10) Required to support products intended for food uses and to supoort products intended for non-food uses if significant exposure of human females of child bearing age may reasonably be expected.

(11) Required to support products intended for food uses and to support products intended for non-food uses if use of the product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).

(12) Required on a case by case basis.

(13) In most cases, where theoretical maximum residue contribution (TMRC) exceeds 50 percent of the maximum permitted intake (MPI), a one year (or longer) interim report on a chronic feed study is required to support a temporary tolerance.

(14) In most cases, where theoretical maxium residue contribution (TMRC) exceeds 50 percent of the maxium permitted intake (MPI), a first generation (or longer) interim report on a multigeneration reproduction study is required to support a temporary tolerance.

(15) A teratology study in one species is required to support a temporary tolerance.

(16) Required if the product consists of, or under conditions of use will result in, an inhalable material (e.g., gas volatile substances, or aerosol/particulate).

(17) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via the oral route.

(ii) Expected human exposure is over a limited portion of the human lifespan, yet is significant in terms of the frequency of exposure, magnitude of exposure, or the duration of exposure (for example, products requiring a temporary tolerance to support an experimental use permit or emergency exemption).

(18) Required if intended use(s) of the pesticide product is expected to result in human exposure to the product, under the following conditions:

(i) Human exposure is via skin contact.

(ii) Expected human skin contact is not purposeful, and such exposure is of limited frequence and duration (for example, such exposure could result from use of certain disinfectant, liquid fumigant or agricultural or home/garden pesticide products, and other circumstances where the Agency determines that more than acute dermal exposure is involved).

(iii) Data from a subchronic 90-day dermal toxicity study are not required.

(19) Required if pesticidal use will involve purposeful application to the human skin or will result in comparable human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing), and if either of the following criteria are met:
(i) Data from a subchronic oral study are not required.
(ii) The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.
(20) Required if either of the following criteria are met:
(i) Use of the pesticide product is likely to result in repeated human exposure to the product, over a significant portion of the human life-span (for example, products intended for use in and around residences, swimming pools, and enclosed working spaces or their immediate vicinity).
(ii) The use requires a tolerance for the pesticide or an exemption from the requirement to obtain a tolerance, or requires issuance of a food additive regulation.
(21) Required if any of the following criteria are met:
(i) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities:
(A) Is structually related to a recognized carcinogen.
(B) Is a substance that cause mutagenic effect as demonstrated by *in vitro* or *in vivo* testing.
(C) Produces in subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that may lead to neoplastic change.
(ii) The use requires a tolerance for the pesticide or exemption from the requirement to obtain a tolerance, or requires the issuance of a food additive regulation.
(iii) Use of the pesticide product is likely to result in human exposure over a portion of the human lifespan which is significant in terms of either the time the exposure occurs or the duration of exposure (for example; pesticides used in treated fabrics for wearing apparel, diapers, or bedding; insect repellents applied directly to human skin; swimming pool additives; constant-release indoor pesticides which are used in aerosol form).
(22)(i) The required battery of mutagenicity tests must include tests appropriate to address the following three categories in accordance with the objectives set forth in §158.202:
(A) Gene mutations.
(B) Structural chromosomal aberrations.
(C) Other genotoxic effects as appropriate for the test substance, e.g., numerical chromosome abberations, direct DNA damage and repair, mammalian cells transformation, target organ/cell analysis.
(ii) Currently recognized tests for each of these categories are listed with the National Technical Information Service (NTIS). Applicants shall explain their reasons for selecting specific tests from the battery of currently recognized tests. Because of the rapid improvements in this field, applicants are encouraged to discuss with the Agency: test selection, protocol design and results of preliminary testing.
(iii) Not required if the pesticide use pattern precludes human exposure (e.g., nonvolatile pesticides packaged and used in enclosed bait boxes).
(23) Required if chronic feeding or oncogenicity studies are required.
(24) Dermal absorption studies required for compounds having a serious toxic effect as identified by oral or inhalation studies, for which a significant route of human exposure is dermal and for which the assumption of 100 percent absorption does not produce an adequate margin of safety. Registrants should work closely with the Agency in developing an acceptable protocol and performing dermal absorption studies.

[49 FR 42881, Oct. 24, 1984. Redesignated and amended at 53 FR 15993, 15999, May 4, 1988; 58 FR 34203, June 23, 1993]

§ 158.390 Reentry protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the reentry protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Foliar dissipation	(1)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	132–1
Soil dissipation	(1), (4)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	132–1
Dermal exposure	(1), (2), (3)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	133–3

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Inhalation exposure ...	(1), (2), (3)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	133–4

Key: CR=Conditionally required; TEP=Typical end-use product.
(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
(1) Data are required if the following conditions are met:
(i)(A) The acute dermal toxicity of the technical grade of active ingredient is less than 200 mg/kg (body weight); or
(B) The acute inhalation toxicity of the technical grade of active ingredient is less than 200 mg/m^3 (for a one-hour exposure); or
(C) The acute oral toxicity of the technical grade of active ingredient is less than 50 mg/kg (body weight); or
(D) Neurotoxic, teratogenic, or oncogenic effects or other adverse effects as evidenced by subchronic, chronic, and reproduction studies would be expected from entry of persons into treated sites; or
(E) The Agency receives other scientifically validated toxicological or epidemiological evidence that a pesticide or residue of a pesticide could cause adverse effects on persons entering treated sites. In the last situation, reentry intervals and supporting data may be required on a case-by-case basis.
(ii) And if: end-use product is to be registered for:
(A) Application to growing crops, such as to or around horticultural and agronomic crops that are field- or orchard-grown.
(B) Application to outdoor tree nursery and forestry operations.
(C) Application to turf crops and commercial applications to turf.
(D) Application to parks and arboretums; or (E) application to aquatic crops.
(iii) And if: human exposure to residues of the pesticide can be reasonably foreseen. This applies primarily to pesticides that will be used on crops where human tasks will involve substantial exposure to residues of the pesticide.
(2) Data required if appropriate surrogate data are not available.
(3) Data required if the applicant chooses to use the allowable exposure level method for proposal of a reentry interval.
(4) Soil dissipation data required if agricultural practice involves human tasks that would cause substantial exposure to residues sorbed to soil.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.440 Spray drift data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the aerial spray drift data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Droplet size spectrum	(1)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	201–1
Drift field evaluation	(1)	CR	CR	CR	CR	.....	.....	CR	.....	.....	TEP	TEP	202–1

Key: CR=Conditionally required; TEP=Typical end use product.
(b) NOTES.—The following are referenced in column two of the table contained in paragraph (a) of this section.
(1) This study is required when aerial applications (rotary and fixed winged) and mist blower or other methods of ground application are proposed and it is estimated that the detrimental effect level of those nontarget organisms expected to be present would be exceeded. The nontarget organisms include humans, domestic animals, fish and wildlife, and nontarget plants. This requirement may be satisfied by submittal of published or unpublished information regarding spray drift patterns that would be expected to be similar to the proposed product.
(2) [Reserved]

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.490 Wildlife and aquatic organisms data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the wildlife and aquatic organisms data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Avian and mammalian testing													
Avian oral LD_{50} (preferably mallard or bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	71–1
Avian dietary LC_{50} (preferably mallard and bobwhite).	(1)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	71–2
Wild mammal toxicity	(2)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	71–3
Avian reproduction (preferably mallard and bobwhite).	(3)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	71–4
Simulated and actual field testing—mammals and birds.	(2)	CR	CR	CR	CR			CR	CR		TEP	TEP	71–5
Aquatic organism testing													
Freshwater fish LC_{50} (preferably rainbow and bluegill).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	72–1
Acute LC_{50} freshwater invertebrates (preferably *Daphnia*).	(1), (7)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	72–2
Acute LC_{50} estuarine and marine organisms.	(4), (7)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	72–3
Fish early life stage and aquatic invertebrate life-cycle.	(5)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	72–4
Fish—life-cycle	(6)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	72–5

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food Crop	Nonfood	Food crop	Nonfood						
Aquatic organism accumulation.	(8)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TGAI, PAI, or degradation product.	TGAI, PAI, or degradation product.	72–6
Simulated or actual field testing—aquatic organisms.	(2)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	72–7

Key: R=Required; CR=Conditonally required; [ ]=Brackets (ie. [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought; TGAI=Techical grade of the active ingredient; TEP=Typical end-use product; PAI="Pure" active ingredient.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1)(i) Data are required as follows to support manufacturing use products and those end-use products for indoor use for which there is no registered manufacturing use product:

(A) Solid formulation indoor use products require avian oral LD_{50} (bobwhite), avian dietary LC_{50} (bobwhite), freshwater fish LC_{50} (rainbow trout) and acute LC_{50} freshwater invertebrate *(Daphnia)*.

(B) Liquid formulation indoors use products require all tests listed under (b)(1)(i) of this section except the avian oral LD_{50}.

(ii) Data are not required to support:

(A) Indoor end-use products consisting of a gas/highly volatile liquid or a highly reactive solid.

(B) Indoor end-use products for which there is a manufacturing use product registration.

(2) Tests required on a case-by-case basis depending on the results of lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics.

(3) Data required if one or more of the following criteria are met:

(i) Birds may be subjected to repeated or continued exposure to the pesticide or any of its major metabolite degradation products, especially preceding or during the breeding season.

(ii) The pesticide or any of its major metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in avian feed.

(iii) The pesticide or any of its major metalolites or degradation products is stored or accumulated in plant animal tissues, as indicated by its octanol/water partition coefficient, accumulation studies, metabolic release and retention studies, or as indicated by structural similarity to known bioaccumulative chemicals.

(iv) Any other information, such as that derived from mammalian reproduction studies that indicates the reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the pesticide product.

NOTE: Prior to conducting this test to support the registration of an avicide, the applicant should consult the Agency.

(4) Data required if the product is intended for direct application to the estuarine or marine environment, or the product is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.

(5) Data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (on whichever species is most sensitive to the pesticide as determined from the results of the acute toxicity tests) are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when any one or more of the following conditions apply:

(i) If the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity.

(ii) If any LC_{50} or EC_{50} value determined in acute toxicity testing is less than 1 mg/l; or

(iii) If the estimated environmental concentration in water is equal to or greater than 0.01 of any EC_{50} or LC_{50} determined in acute toxicity testing.

(iv) If the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC_{50} or LC_{50} determined in acute toxicity testing and any of the following conditions exist:

(A) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.

(B) Physiochemical properties indicate cumulative effects.

(C) The pesticide is persistent in water (e.g., half-life in water greater than 4 days).

(6) Data are required if end-use product is intended to be applied directly to water or expected to transport to water from the intended use site, and when any of the following conditions apply:

(i) If the estimated environmental concentration is equal to or greater than one-tenth of the no-effect level in the fish early life-stage or invertebrate life-cycle test.

(ii) If studies of other organisms indicate the reproductive physiology of fish may be affected. NOTE: The applicant should consult the Agency prior to these tests to support the registration of a pesticide.

(7) Data from testing with the applicant's end-use product or a typical end-use product is required to support the registration of each end-use product which meets any one of the following conditions:

(i) The end-use pesticide will be introduced directly not an aquatic environment when used as directed.

(ii) The LC_{50} or EC_{50} of the technical grade of active ingredient is equal to or less than the maximum expected environmental concentration (MEEC) or the estimated environmental concentration (EEC) in the aquatic environment when the end-use pesticide is used as directed.

(iii) An ingredient in the end-use formulation other than the active ingredient is expected to enhance the toxicity of the active ingredient or to cause toxicity to aquatic organisms.
(8) Required if significant concentrations of the active ingredient and/or its principal degradation products are likely to occur in aquatic environments and may accumulate in aquatic organisms.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.540 Plant protection data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the plant protection data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Target area phytotoxicity	(1)	.....	.....	.....	.....	.....	.....	.....	.....	.....	EP	EP	121–1
Nontarget area phytotoxicity.													
Tier I:													
Seed germination/seedling emergence.	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–1
Vegetative vigor	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–1
Aquatic plant growth	(2)	.....	R	.....	R	.....	.....	R	.....	.....	TGAI	TGAI	122–2
Tier II:													
Seed germination/seedling emergence.	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–1
Vegetative vigor	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–1
Aquatic plant growth	(4)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TGAI	TGAI	123–2
Tier III:													
Terrestrial field	(3)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TEP	TEP	124–1
Aquatic field	(4)	.....	CR	.....	CR	.....	.....	CR	.....	.....	TEP	TEP	124–2

Key: CR=Conditionally required; TGAI=Technical grade of the active ingredient; EP=End-use product; TEP=Typical end-use product.
(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.
(1) Data are required for Special Review and certain public health situations.
(2) Data are required for pesticides to be used in forests and natural grasslands. For herbicide used in forest site preparation; the acquatic plant growth tests will be required. Data are required to support products to be used in other locations when any of the following conditions are met:
(i) Phytotoxicity problems concerning the product arise and open literature data are not available to address the problems.
(ii) The product may pose hazards to endangered or threatened species.
(iii) Special Review has been initiated on the product.
(3) Required if a 25 percent or greater detrimental effect was found in 1 or more plant species in the corresponding test of the previous tier.
(4) Required if a 50 percent or greater detrimental effect was found on any plant species in the corresponding test of the previous tier.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.590 Nontarget insect data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the nontarget insect data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use pattern									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Nontarget insect testing—pollinators													
Honey bee acute contact LD_{50}.	(1)	[CR]	[CR]	[CR]	[CR]	.....	.....	[CR]	[CR]	.....	TGAI	TGAI	141–1
Honey bee—toxicity of residues on foliage.	(1), (2)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	141–2
Honey bee subacute feeding study.	(3)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	141–4
Field testing for pollinators.	(4)	CR	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	141–5
Nontarget insect testing—aquatic insects													
Acute toxicity to aquatic insects.	(5)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	142–1
Aquatic insect life-cycle study.	(5)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	142–1
Simulated or actual field testing for aquatic insects.	(5)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	142–3
Nontarget insect testing—predators and parasites.	(5)	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	143–1 thru 143–3

Key: CR=Conditionally required; [ ]=Brackets (ie, [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; TGAI=Technical grade of the active ingredient; TEP=Typical end-use product.

(b) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) Required only if proposed use will result in honey bee exposure.

(2) Required only when formulation contains one or more active ingredients having an acute LD_{50} of less than 1 microgram/bee.

(3) This requirement is reserved pending development of test methodology.

(4) May be required under the following conditions:

(i) Data from the honey bee subacute feeding study indicate adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.).

(ii) Data from residual toxicity studies indicate extended residual toxicity.

(iii) Data derived from studies with organisms other than bees indicate properties of the pesticide beyond acute toxicity, such as the ability to cause reproductive or chronic effects.

(5) This requirement is reserved pending further evaluation to determine what and when data should be required, and to develop appropriate test methods.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.640 Product performance data requirements.

(a) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the product performance data requirements and the substance to be tested.

Kind of data required	(b) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Efficacy of antimicrobial agents													
Products for use on hard surfaces.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–2
Products requiring confirmatory data.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–3
Products for use on fabrics and textiles.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–4
Air sanitizers	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–5
Products for control of microbial pests associated with human and animal wastes.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	CR	.....	EP*	91–7
Products for treating water systems.	(1)	.....	.....	[CR]	.....	.....	.....	.....	.....	CR	.....	EP*	91–8
Efficacy of fungicides and nematicides													
Products for control of organisms producing mycotoxins.	(1)	[CR]	.....	[CR]	.....	[CR]	.....	.....	.....	.....	.....	EP*	93–16
Efficacy of Vertebrate Control Agents													
Avian toxicants	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–5
Avian repellents	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–6
Avian frightening agents	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–7
Bat toxicants and repellents.	(1)	.....	.....	.....	.....	.....	.....	.....	.....	(R)	.....	EP*	96–9
Commensal rodenticides	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	TEP	EP*	96–10
Rodenticides on farm and rangelands.	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–12
Rodent fumigants	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–13
Rodent reproductive inhibitors.	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	(R)	.....	EP*	96–16
Mammalian predacides ..	(1)	(R)	(R)	.....	.....	.....	.....	.....	(R)	.....	.....	EP*	96–17

Key: R=Required; CR=Conditionally required; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply to products for which an experimental use permit is being sought; EP=End-use product* (asterisk identifies those data requirements that end-use applicants (i.e., ''formulators'') must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); MP=Manufacturing use product; TEP=Typical end-use product.

(b) Notes: The following notes are referenced in column two of the table contained in paragraph (a) of this section.

(1) The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.
(2) [Reserved]

[49 FR 42881, Oct. 24, 1984, as amended at 50 FR 46766, Nov. 13, 1985. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.690 Biochemical pesticides data requirements.

(a) *Biochemical pesticide product analysis data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—product analysis data requirements and the substance to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Product identity	.....	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151–10
Manufacturing process ...	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–11
Discussion of formation of unintentional ingredients.	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–12
Analysis of samples	(iii)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI.	EP* and TGAI.	151–13
Certification of limits	.....	[R]	R	[R]	R	[R]	R	R	R	R	MP	EP*	151–15
Analytical methods	.....	R	R	R	R	R	R	R	R	R	MP	EP*	151–16
Physical and chemical properties.	.....	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–17
Submittal of samples	(iv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI, PAI.	EP*, TGAI and PAI.	151–18

Key: R=Required CR=Conditionally required; MP=Manufacturing-use product; EP*=End-use product (asterisk identifies those data requirements that end-use applicants (i.e., "formulators") must satisfy, provided that their active ingredient(s) (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.
(2) NOTES. The following notes are referenced in column two of the table contained in paragraph (a)(1) of this section.
(i) If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under full scale production.
(ii) If the product is not already under full scale production and an experimental use permit is being sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.
(iii) Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end use products will be required on a case-by-case basis. For pesticides in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.
(iv) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(b) *Biochemical pesticides residue data requirements.* (1) Table. Sections 158.50 and 158.100 though 158.102 describe how to use this table to determine the biochemical pesticides—residue data requirements and the substance to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Chemical identity	(i), (ii), (xiv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	153–3
Directions for use	(i), (iii), (xiv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]			153–3
Nature of the residue:													
Plants	(i), (xiv)	[CR]		[CR]		[CR]			[CR]		PAIRA	PAIRA	153–3
Livestock	(i), (iv), (xiv)	[CR]		[CR]		[CR]			[CR]		PAIRA and plant metabolites.	PAIRA and plant metabolites.	153–3
Residue analytical method.	(i), (v), (xiv)	[CR]		[CR]		[CR]			[CR]		TGAI and metabolites.	TGAI and metabolites.	153–3
Magnitude of the residue:													
Crop field trials	(i), (xiv)	[CR]		[CR]		[CR]			[CR]		TEP	TEP	153–3
Processed food/feed	(i), (vi)	[CR]		[CR]		[CR]					EP	EP	153–3
Meat/mild/poultry/eggs.	(i), (vii)	[CR]		[CR]		[CR]				[CR]	TGAI or plant metabolites.	TGAI or plant metabolites.	153–3
Potable water	(i), (viii)			[CR]	[CR]						EP	EP	153–3
Fish	(i), (ix)			[CR]	[CR]						EP	EP	153–3
Irrigated crops	(i), (x)			[CR]	[CR]						EP	EP	153–3
Food handling	(i), (xi)									[CR]	EP	EP	153–3
Reduction of residue	(i), (xii)	[CR]		[CR]		[CR]					Residue of concern.	Residue of concern.	153–3
Proposed tolerance	(i), (xiii)	[CR]		[CR]		[CR]					Residue of concern.	Residue of concern.	153–3
Reasonable grounds in support of the petition.		[CR]		[CR]		[CR]							153–3

Key: CR=Conditionally required data; TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radio labeled; TEP=typical end-use product, MP=Manufacturing-use product; [ ]=Brackets (i.e., [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (b)(1) of this section.

(i) Residue chemistry data requirements shall apply to biochemical pesticide products when any one or more of the following conditions apply:

(A) Tier II or III toxicology data are required, as specified for biochemical agents in (c)(1) of this section.

(B) The application rate of the product exceeds 0.7 ounces (20 grams) active ingredient per acre per application.

(C) The application rate of the product exceeds a level determined to be comparable to 0.7 ounces active ingredient per application but the application rate is not expressable in terms of ounces per acre per application.

(ii) The same chemical identity data as required in (a)(1) of this section are required, with emphasis on impurities that could constitute a residue problem.

(iii) Required information includes crops to be treated, rate of application, number and timing of applications, preharvest intervals, and relevant restrictions.

(iv) Data on metabolism in livestock are required when residues occur on a livestock feed, or the pesticide is to be applied directly to livestock.

(v) A residue method suitable for enforcement of tolerances is needed whenever a numeric tolerance is proposed Exemptions from the requirement of a tolerance will also usually require an analytical method.

(vi) Data on the nature and level of residue in processed food/feed are required when detectable residues could concentrate on processing and thus require establishment of a food additive tolerance.
(vii) Livestock feeding studies are required whenever a pesticide occurs as a residue in an livestock feed. Direct application to livestock uses will require animal treatment residue studies.
(viii) Data on residues in potable water are required whenever a pesticide is to be applied directly to water, unless it can be determined that the treated water would not be used (eventually) for drinking purpose, by man or animals.
(ix) Data on residues in fish are required whenever a pesticide is to be applied directly to water.
(x) Data on residues in irrigated crops are required when a pesticide is to be applied directly to water that could be used for irrigation or to irrigation facilities such as irrigation ditches.
(xi) Data or residues in food/feed in food handling establishments are required whenever a pesticide is to be used in food/feed handling establishments.
(xii) Reduction of residue data are required when the assumption of tolerance level residues results in an unsafe level of exposure. Data on the level of residue in food as consumed will be used to obtain a more precise estimate of potential dietary exposure.
(xiii) The proposed tolerance must reflect the maximum residue likely to occur in crops and meat/milk/poultry/eggs.
(xiv) Residue data for outdoor domestic uses are required if home gardens are to be treated and the home garden use pattern is different from the use pattern on which the tolerances were established.

(c) *Biochemical pesticides toxicology data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides—toxicology data requirements and the substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Tier I:													
Acute oral toxicity	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	152–10
Acute dermal toxicity	(i), (ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution* and TGAI.	152–11
Acute inhalation	(xiv)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	152–12
Primary eye irritation	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152–13
Primary dermal irritation.	(i), (ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP	152–14
Hypersensitivity study.	(iii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP	152–15
Hypersensitivity incidents.	(iv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	.....	.....	152–16
Studies to detect genotoxicity.	(v)	[R]	[CR]	[R]	[CR]	[R]	[CR]	[CR]	[CR]	[CR]	TGAI	TGAI	152–17
Immune response ...	.....	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152–18
90-day feeding (1 spp.).	(vi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–20
90-day dermal (1 spp.).	(vii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–21
90-day inhalation (1 spp.).	(viii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–22

Teratogenicity (1 spp.).	(ix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–23
Tier II:													
Mammalian mutagenicity tests.	(x)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–19
Immune response ...	(xi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–24
Tier III:													
Chronic exposure	(xii)	CR	.....	CR	.....	CR	.....	.....	.....	CR	TGAI	TGAI	152–26
Oncogenicity	(xiii)	CR	.....	CR	.....	CR	.....	.....	.....	CR	TGAI	TGAI	152–29

Key: R=Required; CR=Conditionally Required; MP=Manufacturing-use product; EP*=End-use product (asterisk identifies those data requirements that end-use applicants (i.e. ''formulators'') must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical Grade of the Active Ingredient; [ ]=Brackets (i.e., [R], [CR]] indicate data requirement that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (c)(1) of this section.

(i) Not required if test material is a gas or is highly volatile.

(ii) Not required if test material is corrosive to skin or has pH less than 2 or greater than 11.5; such a product will be classified toxicity category I on the basis of potential eye and dermal irritation effects.

(iii) Required if repeated contact with human skin results under condition of use.

(iv) Incidents must be reported, if they occur.

(v) Required to support non-food uses if use is likely to result in significant human exposure; or the active ingredient or its metabolites is (are) structurally related to a known mutagen, or belongs(s) to any chemical class of compounds containing known mutagens.

(vi) Required if the use requires a tolerance or an exemption from the requirement for a tolerance, or its use requires a food additive regulation; or the use of the product is otherwise likely to result in repeated human exposure by the oral route.

(vii) Required if pesticidal use will involve purposeful application to the human skin or will result in comparable prolonged human exposure to the product, (e.g., swimming pool algaecides, pesticides for impregnating clothing), and if either of the following criteria are met:

(A) Data from a subchronic oral study are not required.

(B) The active ingredient of the product is known or expected to be metabolized differently by the dermal route of exposure than by the oral route, and a metabolite of the active ingredient is the toxic moiety.

(viii) Required if pesticidal use may result in repeated inhalation exposure at a concentration which is likely to be toxic.

(ix) Required if any of the following criteria are met:

(A) Use of the product under widespread and recognized practice may reasonably be expected to result in significant exposure to female humans.

(B) Its use requires a tolerance or an exemption from the requirement for a tolerance, or its use requires issuance of a food additive regulation.

(x) Required if results from any one of the Tier I mutagenicity tests were positive.

(xi) Required if adverse effects are observed in the Tier I immune response studies.

(xii) Required if the potential for adverse chronic effects are indicated based on:

(A) The subchronic effect levels established in the Tier I subchronic oral toxicity studies, the Tier I subchronic dermal toxicity studies or the Tier I subchronic inhalation toxicity studies.

(B) The pesticide use pattern (e.g., rate, frequency, and site of application).

(C) The frequency and level of repeated human exposure that is expected.

(xiii) Required if the product meets either of the following criteria:

(A) The active ingredient(s) or any of its (their) metabolites, degradation products, or impurities produce(s) in Tier I subchronic studies a morphologic effect (e.g., hyperplasia, metaplasia) in any organ that potentially could lead to neoplastic change.

(B) If adverse cellular effects suggesting oncogenic potential are observed in Tier I or Tier II immune response studies or in Tier II mammalian mutagenicity assays.

(xiv) Required if the product consists of, or under conditions of use results in, an inhalable material (e.g., gas, volatile substance, or aerosol/particulate).

(d) *Nontarget organism, fate and expression data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the biochemical pesticides non-target organism, fate and expression data requirements and substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Tier I:													
Avian acute oral	(i), (ii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–6
Avian dietary	(i), (ii), (vi)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–7
Freshwater fish LC_{50}	(i), (ii), (v)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–8
Freshwater invertebrate LC_{50}.	(i), (ii), (vii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–9
Nontarget plant studies.	(iii)		R		R			R			TGAI	TGAI	154–10
Nontarget insect testing.	(iv), (v)	CR	CR	CR	CR	CR	CR	CR	CR		TGAI	TGAI	154–11
Tier II:													
Volatility	(viii)	CR	CR	CR	CR			CR	CR		TEP	TEP	155–4
Dispenser-water leaching.	(ix)	CR	CR	CR	CR			CR	CR		EP	EP	155–5
Adsorption-desorption.	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–6
Octanol/Water Partition.	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–7
U.V. absorption	(xi)	CR	CR	CR	CR			CR	CR		PAI	PAI	155–8
Hydrolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–9
Aerobic soil metabolism.	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–10
Aerobic aquatic metabolism.	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–11
Soil photolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–12
Aquatic photolysis	(x)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	155–13
Tier III:													
Terrestrial wildlife testing.	(xii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	15–12
Aquatic animal testing.	(xiii)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–13
Nontarget plant studies.	(xiv)										TGAI	TGAI	154–14
Nontarget insect testing.	(xv)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–15

Key: R=Required; CR=Conditionally reguired; [ ]=Brackets (i.e., [R], [CR]) indicates data requirements that apply to products for which an experimental use permit is being sought; MP=Manufacturing-use product; TEP=Typical end-Use product; TGAI=Technical grade of the active ingredient; EP=End-use product, PAI=''Pure'' active ingredient.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (d)(1) of this section.

(i) Tests for pesticides intended solely for indoor application will be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors.

(ii) Preferable test species are: bobwhite quail or mallard for avian acute oral and avian dietary studies: rainbow trout for freshwater fish studies; and *Daphnia* for freshwater invertebrate studies on biochemicals.

(iii) Data are required for pesticides to be used in forests and natural grasslands. For herbicides used in forest site preparation; the aquatic plant growth tests will be required. Data are required when to support products to be used in other locations when any of the following conditions are met.

(A) Phytotoxicity problems arise and open literature data are not available.
(B) The product may pose hazards to endangered or threatened species.
(C) A rebuttable presumption against registration Special Review has been initiated on the product.
(iv) Required depending on pesticide mode of action and results of any available product performance data.
(v) Biochemicals introduced directly into an aquatic environment when used as directed shall be tested as specified in § 158.145.
(vi) Not required if pesticide is highly volatile (estimated volatility greater than 5×10^{-5} atm. m^3/mol).
(vii) If the pesticide will be introduced directly into an aquatic environment when used as directed, then it must be tested as indicated in § 158.145.
(viii) Required when results of any one or more of the Tier I tests indicate potential adverse effects on nontarget organisms and the biochemical agent is to be applied on land.
(ix) Required when results of any one or more of the Tier I tests indicate potential adverse effects on nontarget organisms and the biochemical agent is to be applied on land in a passive dispenser.
(x) Required on a case-by-case basis when results of Tier I tests indicate environmental fate data are needed.
(xi) Required when results of Tier I tests indicate potential adverse effects on beneficial insects and the intended route of exposure of the pesticide is through vapor phase contact.
(xii) Required if either of the following criteria are met:
(A) Environmental fate characteristics indicate that the estimated concentration of the biochemical pesticide in the terrestrial environment is equal to or greater than ⅕ the avian dietary LC50 or the avian single dose oral LD_{50} (converted to ppm).
(B) The pesticide or any of its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian feed.
(xiii) Required if environmental fate characteristics indicate that the estimated environmental concentration of the biochemical agent in the aquatic environment is equal to or greater than 0.01 of any EC_{50} or LC_{50} determined in testing required by Tier I aquatic tests.
(xiv) Required if the product is expected to be transported from the site of application by air, soil, or water. The extent of movement will be determined by the Tier II environmental fate tests.
(xv) Required when results of Tier I tests indicate potential adverse effects on nontarget insects and results of Tier II tests indicate exposure of nontarget insects.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

§ 158.740 Microbial pesticides—Product analysis data requirements.

(a) *Microbial pesticides product analysis data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides—product analysis data requirements and the substance to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Product identity manufacturing process.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	151–20
	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–21
Discussion of formation of unintentional ingredients.	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–22
Analysis of samples	(iii)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI.	EP* and TGAI.	151–23
Certification of limits		[R]	R	[R]	R	[R]	R	R	R	R	MP	EP*	151–25
Analytical methods		R	R	R	R	R	R	R	R	R	MP	EP*	151–25
Physical and chemical properties.		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* and TGAI.	151–26

Kind of data required	(2) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Submittal of samples	(iv)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	MP and TGAI, PAI.	EP* TGAI and PAI.	151–27

Key: R=Required; CR=Conditionally required; MP=Manufacturing-use product: EP*=End-use product (asterisk identifies those data requirements that end-use applicants (i.e., ''formulators'') must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical grade of the active ingredient; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (a)(1) of this section.

(i) If an experimental use permit is being sought, a schematic diagram and/or description of the manufacturing process will suffice if the pesticide is not already under scale production.

(ii) If the product is not already under full scale production and an experimental use permit is being sought, a discussion of unintentional ingredients shall be submitted to the extent this information is available.

(iii) Required to support registration of each manufacturing-use product and end use products produced by an integrated formulation system. Data on other end use products will be required on a case-by-case basis. For pesticide in the production stage, a rudimentary product analytical method and data will suffice to support an experimental use permit.

AAAAA(iv) Routinely required for products produced by an integrated formulation system. Required on a case-by-case basis for other products or materials.

(b) *Microbial pesticides-residue data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides-residue data requirements and the substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Residue data	(i)	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	[CR]	.....	.....	153–4

Key: CR=Conditionally required data; EP=End-use product; MP=Manufacturing-use product; [ ]=Brackets (i.e., [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (b)(1) of this section.

(i) Residue data requirements shall apply to microbial pesticides when Tier II or Tier III toxicology data are required, as specified for microbial pesticides in (c)(1) of this section.

(ii) [Reserved]

(c) *Microbial pesticides-toxicology data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides-toxicology data requirements and the substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Tier I:													
Acute oral		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP* dilution and TGAI.	152–30
Acute dermal		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP dilution and TGAI.	152–31
Acute inhalation	(i)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP and TGAI.	EP* or EP Dilution* and TGAI.	152–32
I.V., I.C., I.P. injection.	(ii)	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	TGAI	TGAI	152–33
Primary dermal		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	152–34
Primary eye		[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	[R]	MP	EP*	152–35
Hypersensitivity study.	(iii)	R	R	R	R	R	R	R	R	R	MP	EP*	152–36
Hypersensitivity incidents.	(iv)	CR	CR	CR	CR	CR	CR	CR	CR	CR			152–37
Immune response		[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152–38
Tissue culture	(v)	[R]	R	[R]	R	[R]	R	R	R	R	TGAI	TGAI	152–39
Tier II:													
Acute oral	(vi)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP*	152–40
Acute inhalation	(vii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	MP	EP*	152–41
Subchronic oral	(viii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–42
Acute I.P., I.C.	(ix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–43
Primary dermal	(x)	CR	CR	CR	CR	CR	CR	CR	CR	CR		EP*	152–44
Primary eye	(xi)	CR	CR	CR	CR	CR	CR	CR	CR	CR		EP*	152–45
Immune response	(xii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–46
Teratogenicity	(xiii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–47
Virulence enhancement.	(xiv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–48
Mammalian mutagenicity.	(xv)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–49
Tier III:													
Chronic feeding	(xvi)	CR		CR		CR				CR	TGAI	TGAI	152–50
Oncogenicity	(xvii)	CR		CR		CR				CR	TGAI	TGAI	151–51
Mutagenicity	(xviii)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–52
Teratogenicity	(xix)	CR	CR	CR	CR	CR	CR	CR	CR	CR	TGAI	TGAI	152–53

Key: R=Required; CR=Conditionally required; MP=Manufacturing-use product; EP*=End use product (asterisk identifies those data requirements that end-use applicants (i.e., ''formulators'') must satisfy, provided that their active ingredient(s) is (are) purchased from a registered source); TGAI=Technical Grade of the Active Ingredient; [ ]=Brackets (i.e., [R], [CR]) indicate data requirements that apply when an experimental use permit is being sought.

(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (c)(1) of this section.

(i) Required if 20 percent or more of the aerodynamic equivalent of the product (as registered or under conditions of use) is composed of particulates less than 10 microns in diameter.

(ii) Data required for products as follows:

(A) Intravenous (''IV'') infectivity study for bacterial, and viral agents;
(B) Intracerebral (''IC'') infectivity study for viral and protozoan agents; and
(C) Intraperitoneal (''IP'') infectivity study for fungal and protozoan agents.
(iii) Required if commonly recognized use practices will result in repeated human contact by inhalation or dermal routes.
(iv) Hypersensitivity incidents must be reported, if they occur.
(v) Data required for products whose active ingredient is a virus.
(vi) Required if survival, replication, infectivity, toxicity, or persistence of the microbial agent (virus or protozoa) is observed in the test animals treated in the Tier I acute oral infectivity tests or the intraperitoneal or intracerebral injection test for protozoa.
(vii) Required if survival, replication, infectivity, toxicity, or persistence of the microbial agent (virus or protozoa) is observed in the test animals treated in the comparable Tier I acute inhalation tests.
(viii) Required if there is evidence of survival, replication, infectivity, or persistence of the protozoan agent in the Tier I oral infectivity test.
(ix) Required if in Tier I acute oral infectivity testing, Tier I dermal toxicity/infectivity testing, or Tier I intraperitoneal or intracerebral injection testing, the test microorganism (bacteria, fungi, or protozoa) survived for more than 2 weeks, caused toxic effects, or caused a severe illness response in an experimental animal as evidenced by irreversible gross pathology, severe weight loss, toxemia, or death.
(x) Required if infectivity or if marked edema or broad erythema was observed in the Tier I dermal irritation study.
(xi) Required if infectivity or if severe ocular lesions are observed in the Tier I primary eye irritation study.
(xii) Required if results of the Tier I immune response test indicate abnormalities.
(xiii) Required when Tier I tests on viral agents show replication of the virus in mammalian hosts and significant damage to mammalian cells.
(xiv) Required when Tier I infectivity tests on bacteria or fungi indicate prolonged survival (including presence of viable microbial agents in test animal excreta) and/or multiplication (infectivity) of the bacteria or fungal agent, respectively.
(xv) Required if any of the following criteria are met:
(A) Acute infectivity tests are positive in Tier I studies.
(B) Adverse effects are observed in immune response studies.
(C) Positive results are obtained in tissue culture tests with viral agents.
(xvi) Required when the potential for chronic adverse effects (e.g., replication or persistence of viral or subviral constituents, protozoans, fungi, or bacteria) are demonstrated by any of the Tier II tests (except primary dermal, primary ocular, and mammalian mutagenicity tests).
(xvii) Required when the potential for oncogenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents, or bacteria, fungi or protozoans; or mutagenic effects) by any of the Tier II tests except the primary dermal and primary ocular studies.
(xviii) Required when the potential for mutagenic effects is indicated (e.g., adverse cellular effects due to presence, replication, or persistence of viral or subviral constituents, bacteria, fungi or protozoa) by any of the Tier II tests except primary dermal or primary ocular studies.
(xix) Required when the potential for teratogenic effects is expected based on the presence of persistence of fungi, bacteria, viruses, or protozoa in mammalian species as a result of testing performed in Tier II, except primary dermal and primary ocular studies.

(d) *Microbial pesticides non-target organism and environmental expression data requirements*—(1) Table. Sections 158.50 and 158.100 through 158.102 describe how to use this table to determine the microbial pesticides non-target organism and environmental expression data requirements and substances to be tested.

Kind of data required	(2) Notes	General use patterns									Test substance		Guidelines reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Tier I:													
Avian oral	(i), (ii), (iii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–16
Avian injection test	(i), (ii), (iii)	[R]	[R]	[R]	[R]	CR	CR	[R]	[R]	CR	TGAI	TGAI	154–17
Wild mammal testing	(iv)	CR	CR	CR	CR			CR	CR		TGAI	TGAI	154–18
Freshwater fish testing.	(i)	[R]	[R]	[R]	[R]	CR	CR	[R]	CR	CR	TGAI	TGAI	154–19

Freshwater aquatic invertebrate testing.	(i)	[R]	[R]	[R]	CR	CR	[R]	CR	CR	TGAI	TGAI	154–20	
Estuarine and marine animal testing.	(v)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	154–2	
Nontarget plant studies.	.....	[R]	[R]	[R]	.....	.....	[R]	[R]	CR	TEP	TEP	154–2	
Nontarget insect testing.	.....	[R]	[R]	[R]	CR	CR	[R]	[R]	.....	TGAI	TGAI	154–23	
Honey bee testing ...	.....	[R]	[R]	[R]	CR	CR	[R]	[R]	.....	TGAI	TGAI	154–24	
Tier II:													
Terrestrial environmental testing.	(vi)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI or TEP.	TGAI or TEP.	155–18	
Freshwater environmental expression tests.	(vii)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI or TEP.	TGAI or TEP.	155–19	
Marine or estuarine environmental expression tests.	(xiii), (ix)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI or TEP.	TGAI or TEP.	155–20	
Tier III:													
Terrestrial wildlife and aquatic organism testing.	(x)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI or TEP.	TGAI or TEP.	154–25	
Avian pathogenicity/reproduction test.	(xi)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	154–26	
Definitive aquatic animal tests.	(xii)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	154–27	
Aquatic embryo larvae and life cycle studies.	(xiii)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	154–28	
Aquatic ecosystem test.	(xiv)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TGAI	154–29	
Special aquatic tests (reserved).	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	154–30	
Nontarget plant studies.	(xv)	CR	CR	CR	.....	.....	CR	CR	.....	TGAI	TEP	154–31	
Tier IV:													
Simulated and actual field tests (birds, mammals).	(xvi) (xiii)	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	154–33	
Simulated and actual field tests (aquatic organisms).	(xvii), (xviii)	CR	CR	CR	.....	.....	CR	CR	.....	TEP	TEP	154–34	
Simulated and actual field tests (insect predators, parasites) (reserved).	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	154–35	

Kind of data required	(2) Notes	General use patterns									Test substance		Guideline reference No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Domestic outdoor	Indoor use	Data to support MP	Data to support EP	
		Food crop	Nonfood	Food crop	Nonfood	Food crop	Nonfood						
Simulated and actual field tests (insect pollinators) (reserved).	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	154–36

AAAAAKey: R=Required; CR=Conditionally required; [ ]=Brackets (i.e., [R], [CR]) indicates data requirements that apply to products for which an experimental use permit is being sought; MP=Manufacturing-use Product; TEP=Typical end-use product; TGAI=Technical grade of the active ingredient; EP=End-use product; PAI=''Pure'' active ingredient.

AAAAA(2) NOTES.—The following notes are referenced in column two of the table contained in paragraph (d)(1) of this section.

AAAAA(i) Tests for pesticides intended solely for indoor application will be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors.

AAAAA(ii) Preferable test species are: bobwhite quail or mallard for avian acute oral and avian dietary studies; rainbow trout for freshwater fish studies.

AAAAA(iii) Data from *either* the avian acute oral *or* the avian injection study are required to support an experimental use permit.

AAAAA(iv) Required on a case-by-case basis if results of tests required by paragraph (c)(1) of this section are inadequate or inappropriate for assessment of hazards to wild animals.

AAAAA(v) Required when product is intended for direct application into the estuarine or marine environment or expected to enter this environment in significant concentrations because of expected use or mobility pattern.

AAAAA(vi) Required when toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents:

AAAAA(A) Avian single dose oral toxicity and pathogenicity tests.

AAAAA(B) Avian injection pathogenicity tests.

AAAAA(C) Wild mammals toxicity and pathogenicity test.

AAAAA(D) Plant studies—terrestrial.

AAAAA(E) Honey bee toxicity/pathogenicity test.

AAAAA(F) Testing for toxicity/pathogenicity to insect predators and parasites.

AAAAA(vii) Required when toxic or pathogenic effects are observed in any of the following Tier I test for microbial pest control agents:

AAAAA(A) Freshwater fish toxicity and pathogenicity testing.

AAAAA(B) Freshwater aquatic invertebrate toxicity and pathogenicity test.

AAAAA(C) Plant studies—aquatic.

AAAAA(viii) Required if product is applied on land or in fresh water and toxic or pathogenic effects are observed in any of the following Tier I tests for microbial pest control agents:

AAAAA(A) Estuarine and marine animal toxicity and pathogenicity test.

AAAAA(B) Plant studies—estuarine or marine.

AAAAA(ix) Required if product is applied in marine or estuarine environments and toxic or pathogenic effects are observed in any of the following Tier I tests:

AAAAA(A) Avian single dose oral toxicity and pathogenicity test.

AAAAA(B) Avian injection pathogenicity test.

AAAAA(C) Estuarine and marine animal toxicity and pathogenicity test.

AAAAA(x) Required when toxic effects on nontarget terrestrial wildlife or aquatic organisms are reported in one or more Tier I tests and results of Tier II tests indicate exposure of the mocrobial agent to the affected nontarget terrestrial wildlife or aquatic organisms.

AAAAA(xi) Required when:

AAAAA(A) Pathogenic effects are observed in Tier I avian tests at a level equal to the adjusted host equivalent amount.

AAAAA(B) Chronic, carcinogenic, or teratogenic effects are reported in tests required by paragraph (c)(1) of this section for evaluating hazard to humans and domestic animals.

AAAAA(C) Tier II Environmental expression testing indicates that exposure of terrestrial animals to the microbial agent is likely.

AAAAA(xii) Required when product is intended for use in water or expected to be transported to water from the intended use site, and when pathogenicity or infectivity was observed in Tier I tests.

AAAAA(xiii) Required when both of the following conditions are met:

AAAAA(A) Pathogenic effects at actual or expected field residue exposure levels are reported in Tier III.

AAAAA(B) The agency determines that quarantine methods will prevent the microbial pest control agent from contaminating areas adjacent to the test area.

AAAAA(xiv) Required if, after an analysis of the microbial agent's properties, the individual use patterns, and the results of previous nontarget organism and environmental expression tests, it is determined that use of the microbial agent may result in adverse effects on the nontarget organisms in aquatic environments, including those of the water column and bottom sediments. When a microbial pest control agent is used in or is expected to transport to water from the intended use site, major considerations for requiring these infectivity tests include, but are not limited to:

AAAAA(A) Infectivity or pathogenicity demonstrated in previous testing.

AAAAA(B) Viability of the microorganism in natural waters as demonstrated in Tier II tests.

AAAAA(xv) Required if the product is transported from the site of application by air, soil, or water or transmission by other animals. The extent of movement will be determined by the environmental expression tests in Tier II.

AAAAA(xvi) The Agency expects that Tier IV requirements would be imposed retrospectively—after product registration as post registration monitoring, since it is unlikely a registrant would pursue registration of a microbial agent posing potential hazards such that testing beyond Tier III is required.

AAAAA(xvii) Short term simulated or actual field studies are required when it is determined that the product is likely to cause adverse short-term or acute effects, based on consideration of available laboratory data, use patterns, and exposure rates.

AAAAA(xviii) Data from a long-term simulated field test (e.g., where reproduction and growth of confined populations are observed) and/or an actual field test (e.g., where reproduction and growth of natural populations are observed) are required if laboratory data indicate adverse long-term, cumulative, or life-cycle effects may result from intended use.

[49 FR 42881, Oct. 24, 1984. Redesignated at 53 FR 15993, May 4, 1988, and amended at 58 FR 34203, June 23, 1993]

APPENDIX A TO PART 158—DATA REQUIREMENTS FOR REGISTRATION: USE PATTERN INDEX

How to use this Index:

1. Identify the Pesticide Use Site Group listed below (e.g., agricultural crops, forests, ornamental plants) that covers the specific use pattern of interest to you.

2. Find your specific use pattern under the appropriate Pesticide Use Site Group.

3. Identify the general use pattern that corresponds to your specific use pattern.

4. Use the general use pattern in determining applicable data requirements on the Data Requirements tables presented in §§ 158.120 through 153.170.

Pesticide use site group

1. Agricultural Crops.
2. Ornamental Plants and Forest Trees.
3. General Soil Treatment and Composting.
4. Processed or Manufactured Products, and food or feed containers or dispensers.
5. Pets and Domestic Animals.
6. Agricultural Premises and Equipment.
7. Household.
8. Wood or Wood Structure Protection Treatments.
9. Aquatic sites.
10. Noncrop, wide area, and general indoor/outdoor treatments.
11. Antifouling treatments.
12. Commercial and Industrial Uses.
13. Domestic and Human Use.
14. Miscellaneous Indoor Uses.

Specific use patterns—listed according to use site group	Corresponding general use pattern
1. *Agricultural crops*	
Small fruits	Terrestrial food crop
Caneberries (e.g., raspberry, dewberry)	
Bushberries (e.g., blueberry, currant)	
Vine fruits (e.g., grape, kiwi fruit)	
Strawberry	
Cranberry	
Pome fruits (e.g., apple, quince)	
Stone fruits (e.g., peach, cherry)	
Nut crops—tree & shrub (e.g., pecan, filbert)	
Other temperate fruits (e.g., persimmon, pawpaw)	
Tropical and subtropical fruits	
Citrus	
Banana and plantain	
Palm fruits and nuts (e.g., date, coconut)	
Pineapple	
Other fruits and nuts	
Beverage crops	
Woody—cocoa, coffee, tea	
Herbaceous—chicory, mint	
Flavoring and spice crops	
Woody—leaf/stem, root, seed and pod	
Herbac.—leaf/stem, root, seed and pod	
Vegetables—leaf/stem, root, seed and pod, fruiting vegetables, cucurbits	
Commercial annual (e.g., tomato, bean)	
Commercial perennial (e.g., asparagus, rhubarb)	
Greenhouse (commercial)	Greenhouse food crop
Mushrooms	
Nursery/seed crop/medical crop/tobacco	Greenhouse nonfood crop
Fiber crops	Terrestrial food crop
Cotton	
Others—(e.g., flax)	
Forage crops	
Typical grasses—annual (e.g., sudan grass)	
Typical grasses—perennial (e.g., bromegrass)	
Corn and sorghum	
Small grains for forage (e.g., rye)	
Perennial legumes (e.g., white clover)	
Annual legumes (e.g., crotalaria, soybean)	
Crop harvest residue (peanut vines, beet tops, etc.)	
Grain and edible seed crops	
Corn	
Rice	Aquatic food crop
Wheat, barley, rye, oats	Terrestrial food crop
Sorghum	
Alfalfa	
Other grains	
Other nongrains (e.g., squash, pumpkin)	
Buckwheat	
Sesame	
Peanut	
Sunflower	
Seed sprout crops	
Mung bean, red clover, soybean, alfalfa, etc.	
Nonlegume crops (e.g., wheat, radish, black mustard)	
Crops grown exclusively for seed for planting	
Sugar crops	
Stored raw agricultural commodities	Indoor
Honey (principal nectar-producing crops)	
Sugar beet	
Sugar cane	
Sugar maple	
Sorghum (for sugar)	
Crops for smoking and chewing	Terrestrial nonfood crop
—field	
—shade	
—storage	
—greenhouses	
Sapodilla (for chewing gum)	Terrestrial food crop
Oil crops	
Annual herbaceous crops	
Perennial herbaceous crops	
Tropical/subtropical woody crops	
Drug and medicinal crops	Terrestrial nonfood crop
Annual herbaceous crops	
Perennial herbaceous crops	
Temperate woody crops	
Tropical/subtropical wood crops	
2. *Ornamental plants and forest trees*	
Ornamental plants	Terrestrial nonfood crop

Specific use patterns—listed according to use site group	Corresponding general use pattern
Annual garden plants	
Temperate perennial nonfood garden herbs	
Commercial greenhouse crops	Greenhouse nonfood crop
Houseplants	Indoor
Home and retail greenhouse and conservatory plants	
Public display plantings	Terrestrial nonfood crop
Bulb, corm, and tuber ornamentals	
Subtropical/tropical garden evergreen plants (dry—e.g., agave)	
Subtropical/tropical garden evergreen plants (moist—e.g., ferns)	
Groundcovers	
Aquatic plants (e.g., waterlilies)	Aquatic nonfood use
Ornamental trees, shrubs, and vines (woody)	Terrestrial nonfood crop
Deciduous temperate broadleaf	
Evergreen temperate broadleaf	
Deciduous temperate conifer	
Evergreen temperate conifer	
Tropical/subtropical broadleaf	
Tropical/subtropical conifer	
Tropical/subtropical miscellaneous (e.g., cycad, tree fern, bamboo)	
Lawn and turf grasses—ornamental	Terrestrial nonfood crop or domestic outdoor
Cool season Winter grasses (bent, bluegrass, fescue, etc.)	
Summer grasses (zoysia, bermudagrass, etc.)	
Ornamental bunch grasses (pampasgrass, blue fescue)	
Forest trees—nonornamental—trees forests, plantings	Forestry
Deciduous temperate (broadleaf)	
Evergreen temperate (broadleaf)	
Deciduous and evergreen conifers	
Tropical/subtropical broadleaf	
Tropical/subtropical conifer	
Forest tree nurseries—Temperate broadleaf trees	
Temperate conifer trees	
Forest trees: dead trees/logs/stumps in the forest or in plantings	
3. *General soil treatment and composting*	
General soil treatments	Terrestrial nonfood crop
Soil application with no mention of crops to be grown (potting soil, top soil).	
Manure	
Composts	
Cull piles	
Mulches	
4. *Processed or manufactured products, and food or feed containers or dispensers*	
Processed vegetables, fruits, and nuts	Indoor
Fruits	
Leafy vegetables	
Root vegetables	
Fruited vegetables	
Nuts	
Peanuts	
Seeds (sesame, sunflower)	
Dried processed	
Fruits	
Vegetables	
Tobacco	
Beverages (tea, coffee)	
Herbs and spices	
Animal Feeds	
Cattle (beef)	
Cattle (dairy)	
Goat (nondairy)	
Goat (dairy)	
Horse, mule, donkey	
Poultry (chicken, turkey, etc.)	
Sheep (meat)	
Sheep (wool)	
Swine	
Dog	
Cat	
Other pets (including birds)	
Fur-bearing stock	
Other meat-producing stock (e.g., rabbit)	
Fish food (commercial)	
Fish food (pet)	
Birdseed	
Processed grain products for human consumption	
Corn	
Soybean	
Wheat	
Other grains (rice, barley, etc.)	
Cereal foods	
Flour	
Baked goods	
Farinaceous products	
Processed animal products for human consumption	
Cheese	
Egg yolks	
Meats, including fish and poultry	
Milk	
Processed plant products for human consumption	
Chocolate	
Candy	
Sugar	
Yeast	
Citrus pulp	
Chewing gum	
Cigarettes, etc.	
Herbs and spices	
Pickles	
Glazed fruits	
Jellies	
Seed oils	
Fruit syrups (e.g., cola)	
Fruit juices	
Fermentation beverages (wine, beer, whiskey, vinegar)	
Processed or manufactured nonfood plant and animal products	
Textiles, fabrics, fibers	
Fur and hair products	
Leather products	
Food and feed containers, dispensers, and processing equipment	
Airtight storages—large (empty/full)	
Airtight storages—small (empty/full)	
Fumigation chambers	
Bins	
Elevators	
Storage areas—(empty/full)	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Processing or handling equipment and machinery (other than food processing)	
5. *Pets and domestic animals—animals and their man-made premises*	
Dairy cattle—lactating	Indoor
Dairy cattle—nonlactating	
Dairy cattle—heifers, calves	
Goats—lactating	
Goats—nonlactating	
Goats—young (kids)	
Fur- and wool-bearing animals	
Goats	
Sheep	
Mink	
Chinchilla	
Rabbit	
Fox	
Nutria	
Meat animals (mammals)	
Cattle (and calves)	
Goats (and kids)	
Horses	
Rabbits	
Sheep (and lambs)	
Swine	
Bison	
Reindeer	
Poultry (meat, eggs)	
Chickens	
Turkeys	
Ducks, geese	
Guineas, pheasants, quail, etc.	
Honey production	
Bees	
Beehives	
Honeycombs	
Fish and shellfish production	Aquatic food use
Hatchery buildings	
Culture ponds, containers	
Animals for labor, display, riding, racing, lab use, etc.	Indoor
Dogs	
Horses, donkeys, mules	
Guinea pigs	
Mice	
Rats	
Gerbils	
Hamsters	
Monkeys	
Cats	
Chickens, birds	
Wild rodents	
Alfalfa leafcutting bee (pollinator)	
Alkaline bee (pollinator)	
Zoo ruminants	
Zoo ungulates	
Zoo canines	
Zoo felines	
Zoo primates	
Zoo reptiles	
Zoo amphibians	
Zoo birds	
Zoo—others	
Aquarium fish	
Animals for pets, including their cages, bedding, nests, etc.	
Dogs	
Cats	
Birds	
Rodents	
Lagomorphs	
Fish	
Amphibians	
Reptiles	
Primates	
Other vertebrates	
6. *Agricultural premises and equipment*	
Egg handling facilities and equipment	Indoor
Egg washers	
Egg rooms	
Hatching egg treatments	
Hatching egg rooms	
Hatching egg equipment	
Egg packing plants and hatcheries	
Milk handling facilities and equipment	
Milk storage rooms	
Milking stalls and parlors	
Milking machines, milk tanks, etc.	
Teat cups, liners, etc.	
Milk processing equipment	
7. *Household*	
Non-food area and sites	Indoor
Closets, storage areas	
Basements, cellars	
Bedrooms	
Attics	
Recreation rooms	
Living rooms	
Baseboards, window sills, etc.	
Plumbing fixtures	
Sickrooms	
Food-handling and food storage areas	
Kitchens	
Dining rooms	
Pantry and food storage shelving	
Household contents and space	
Air	
Beds	
Rugs	
Book cases	
Furs, fabrics, blankets	
Play pens	
Sickroom utensils	
Filters for air vents, air conditioners, furnaces, etc.	
Outdoor areas (Noncommercial homeowner use)	Domestic outdoor or terrestrial food crop
Home garden, orchards	
Porches	Domestic outdoor
Patios	
Foundations	
Steps	
Eaves	
Yards, lawn, turf	
Domestic ornamental plantings	
8. *Wood or Wood Structure Protection Treatments*	
Buildings (for termite, powderdust beetle controls, etc.)	Domestic outdoor or indoor
Unseasoned forest products	
Seasoned forest products	
Finished wood products	
Wood pressure treatments	
Plant-growing wood structures and containers	
Wood containers for nonfood, nonfeed uses	
9. *Aquatic sites*	
Food processing water systems	Aquatic food crop

Specific use patterns—listed according to use site group	Corresponding general use pattern
Poultry and livestock drinking water	
Pulp and papermill systems	Aquatic noncrop
Swimming pool water	
Industrial disposal systems	
Industrial ponds	
Human drinking water	Aquatic food crop
Cooling water towers	Aquatic noncrop
Agricultural irrigation water, and ditches	Aquatic food crop
Agricultural drainage water and ditches	
Sewage systems and drainfields	Aquatic noncrop
Dishwashing water	Indoor
Domestic and commercial nonpotable water	Aquatic noncrop
Lakes, ponds, impounded water	
Streams, rivers, canals	
Swamps, marshes, wetlands	
Air conditioner water	
Humidifier water	
Air washer water systems	
Secondary oil recovery injection water	
Heat exchange water system	
Polluted water	
Bait boards (floating—for vertebrate control)	
Catch basins, puddles, tree holes	
Estuaries, tidal marshes	
Commercial and sport fish-bearing waters	Aquatic food crop
10. *Noncrop, wide area, and general indoor/outdoor treatments*	
Uncultivated agricultural areas (nonfood producing)	Terrestrial noncrop
Farmyards	
Fuel storage areas	
Fence rows	
Rights-of-way	
Fallow land	Terrestrial food crop
Soil bank land	Terrestrial noncrop
Barrier strips	
Uncultivated nonagricultural areas (outdoor)	
Airports	
Recreation areas, fairgrounds, race tracks, tennis courts, etc.	
Campgrounds	
Recreation area structures	
Highway rights-of-way	
Railroad rights-of-way	
Utility rights-of-way	
Sewage disposal areas	
Industrial sites (lumberyards, tank farms, etc.)	
Paved areas	
Private roads and walks	
Fencerows and hedgerows (nonagricultural)	
Directed Pest Control to Pests' Nests, etc., and for Traps	Terrestrial noncrop or indoor
Diseased beehives	
Nuisance bee nests	
Ant mounds, hills, dens	
Termite mounds	
Insect traps (chemical lures)	
Repellents and irritants to pests (when not covered by other sites)	
Wide area and general indoor/outdoor treatments	
Rural areas (unspecified)	
Urban areas (unspecified)	
Public buildings and structures	
Animal burrow entrances, dens, tunnels	
Animal nests	
Animal trails	
Mammal feeding areas	
Nonagricultural areas for public health treatments	
Bird roosting, nesting areas	
Bird feeding areas	
11. *Antifouling Treatments*	
Sites for marine exposures	Aquatic noncrop
Boat bottoms and other submersed structures	
Steel	
Fiberglass	
Aluminum	
Wood	
Plastic	
Other substances and materials	
Crab pots and lobster pots	
Sites for fresh water exposures	
Cooling tower influent conduits	
12. *Commercial and Industrial Uses*	
Transportation Facilities	Indoor
Bus	
Truck and Trailer	
Containerized units	
Railroad cars	
Aircraft	
Ships/barges	
Auto, taxis	
Recreational vehicles	
Shipping containers	
Food and feed processing plants	
Bakeries	
Bottlers	
Canneries	
Dairies, creameries, milk processing plants	
Feed mills, feed stores	
Fresh fruit packing and processing	
Meat processing	
Poultry processing	
Wineries, wine cellars	
Flour mills, machinery, warehouses, bins, elevators	
Egg processing	
Candy and confectionary plants	
Sugar processing, cane mills, etc.	
Cider mills	
Dry food products plants	
Tobacco processing	
Air treatment for processing and transportation of foods	
Beverage processing	
Nut processing	
Cereal processing	
Seafood processing	
Vegetable oil processing	
Spice mills	
Vinegar processing	
Farinaceous processing (noodles, etc.)	
Mushroom processing	
Dried fruit processing	
Pickle processing	
Ice plants	
Chocolate processing	
Fruit juice processing	
Eating establishments (all)	
Food handling areas	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Food serving areas	
Eating establishment nonfood areas	
Air treatment for eating establishments	
Food storage equipment (coolers, refrigerators, etc.)	
Eating and serving utensils (spoons, etc.)	
Food marketing, storage, and distribution	
Food dispensing and vending equipment	
Food stores, markets, stands	
Meat and fish markets	
Food catering facilities	
Food marketing, storage, and distribution equipment and utensils	
Hospitals and related institutions and facilities	
Critical premises (e.g., burn wards, etc.)	
Hospital patient premises (wards, emergency rooms, etc.)	
Noncritical premises (labs, lounges, lobbies, storage)	
Critical items (hypodermic needles, dental instruments, catheters, etc.)	
Noncritical items (bedpans, carpets, furniture, etc.)	
Air treatment (also to ambulances)	
Janitorial equipment	
Barber and beauty shop instruments and equipment	
Morgues, mortuaries, and funeral homes	
Premises (embalming rooms, etc.)	
Equipment (tables, etc.)	
Instruments	
Burial vaults, mausoleums	
Air treatment	
Commercial, institutional, and industrial Maintenance, Buildings, and Structures	
Locker rooms, equipment	
Gyms, bowling alleys, and equipment	
Telephones and booths	
Shower rooms, mats, and equipment	
Cotton mill premises and equipment	
Auditoriums and stadiums	
Factories	
Rendering plants	
Loading areas, ramps	
School buildings and equipment	
Office buildings	
Laundries	
Fuels from Crops (alcohol, methane)	
Fossil fuels (e.g., oils, jet fuel)	
Seed oils	
Paper	
Pesticide materials preservation and protection	
Rodenticide baits (protection against insects)	
Dried plant parts (pyrethrum, red squill, rotenone, sabadilla)	
Paints	
Preservatives and protectants	
Grains	
Hay, silage	
Adhesives	
Coatings (asphalt and lacquer)	
Fuels	
Leather and leather products	
Leather processing liquors	
Metalworking cutting fluids	
Oil recovery drilling muds and packer fluids	
Paints (latex)	
Paper and paper products	
Plastic products	
Resin emulsions	
Rubber (natural) products	
Specialty products (polishes, cleansers, dyes, etc.)	
Textiles, textile fibers, and cordage	
Wet-end additives, etc. (pulp sizing, alum, casein, printing pastes)	
Disposable diapers	
Wool, hair, mohair, furs, felt, feathers, etc.	
Electrical supplies, cables, and equipment	
13. *Domestic and Human Use*	
Human Body and Hair	Indoor
Fiber product protection (Moth, mildew-proofing)	
Clothing	
Upholstery	
Ornamental fabrics (draperies, tapestries)	
Ropes	
Sail cloth	
Human articles and materials	
Bedding, blankets, mattresses	
(Treatments to) hair, body, clothing (while being worn)	
Clothing	
Face gear (goggles, face masks, etc.)	
Headgear (safety helmets, headphones, etc.)	
Wigs	
Contact lenses	
Dentures, toothbrushes, mouthpieces to musical instruments, etc.	
Brick, asbestos, etc.	
Wood surfaces	
Leather surfaces	
Fabric surfaces	
Paper/paperboard surfaces	
Specialty uses	
Museum collectors (preserved animal and plant specimens)	
Military uses—not specified	
Quarantine uses—not specified	
DHHS/FDA uses—not specified	
Filters (air conditioning, air, and furnace)	
Biological specimens	
Underground cables	
Cuspidors, spittoons	
Vomitus	
Human wastes	
Air sanitizers	
Diapers	
Laundry equipment (carts, chutes, tables, etc.)	
Dust control—products and equipment (mops, etc.)	
Dry cleaning	
Carpets	
Upholstery	
Bathrooms, toilets bowls, and related sites	
Bathroom premises	
Toilet bowls and urinals	

Specific use patterns—listed according to use site group	Corresponding general use pattern
Toilet tanks	
Portable toilets, chemical toilets	
Vehicular holding tanks	
Bathroom air treatment	
Diaper pails	
Refuse and soild waste	
Refuse and solid waste containers	
Refuse and solid waste transportation and handling equipment	
Garbage dumps	
Household trash compactors	
Garbage disposal units, food disposals	
Incinerators	
14. *Miscellaneous Indoor Uses*	
Surface Treatments	Indoor
Hard nonporous surfaces (painted, tile, plastic, metal, glass, etc.)	
Hard porous surfaces (cement, plaster)	
Camping equipment and gear	
Grooming instruments (brushes, clippers, razors, etc.)	
Laundry, cleaning, and dry cleaning	